HHS:PHS:FDA:HFP:OMFS:ODSS:DDS:DSPB

5001 Campus Drive
College Park, MD 20740-3835

M-b-385

September 2, 2025

TO: Chief, Dairy Operations East Branch
Chief, Dairy Operations West Branch
Attn: FDA Milk Specialists

FROM: Milk Safety Policy Branch (HFS-316)

SUBJECT: Endress+Hauser Memograph M RSG45

Milk Specialists from FDA's Dairy Operations Branches and subject matter experts from FDA's Dairy Safety Policy Branch, in consultation with the Atlantic Midwest Dairy Equipment Review Committee (AMDERC), have evaluated and validated the technical information submitted by Endress+Hauser addressing the Endress+Hauser Memograph M RSG45 (RSG45).

When constructed, installed, and operated as described in this memorandum, the RSG45 has been found to comply with Appendix H., Section VI. Criteria for the Evaluation of Computerized Systems for Grade "A" Public Health Controls of the *Grade "A" Pasteurized Milk Ordinance* (PMO) when used as a Pasteurization Safety Thermal Limit Recorder (STLR) and/or Flow Recorder/Controller (FRC). In addition, the RSG45 has been found to comply with the Appendix H., Section V. requirements for electronic data collection, storage, and reporting. Compliance with the PMO is based upon construction, installation, and operation as described in the attached *Endress+Hauser RSG45/FDM PMO* manual (revision 1.25, Attached) and *Appendix I Memograph M RSG45* document (attached) which identifies basic configuration values and test procedures to be reviewed during verification. The RSG45 units that are configured with PMO-compliant options will have "M-b-385" printed on the nameplate.

The unit was reviewed for compliance with firmware version ENX200A 2.06.00. Updated firmware does not necessarily indicate non-compliance, but the Regulatory Agency should verify that the changes in the firmware do not adversely affect public health controls.

Note that the RSG45 also has the capability to function as a differential pressure controller. However, this function has not been reviewed. Therefore, applications where the RSG45 operates as a differential pressure controller should be individually evaluated by the Regulatory Agency.

For information regarding this equipment, please contact:

Endress+Hauser USA
2350 Endress Place
Greenwood, IN 46143
317-535-2280
Attn: Ola Wesstrom, ola.wesstrom@endress.com

FDA's review and acceptance of this piece of equipment does not constitute FDA endorsement or approval. Any representation on a label or in printed literature citing or indicating as "FDA Approved" is false and misleading.

An electronic version of this memorandum is available for distribution to FDA Milk Specialists, State Milk Regulatory / Agencies and Milk Sanitation Rating Officers. The electronic version should be widely distributed to representatives of the dairy industry and other interested parties and will be available on the FDA Web Site at https://gams.fda.gov/ at a later date.

Please direct questions or concerns regarding this M-b to HFP-Dairy@fda.hhs.gov.

Operating instructions
Memograph M RSG45 and Field Data Manager (FDM)

Digital recorder and reporting software for secure data management and visualization per PMO (Pasteurized Milk Ordinance) installations compliant per M-b-385

Endress+Hauser
People for Process Automation

Introduction and system description

Memograph M RSG45 data manager hardware and Field Data Manager (FDM) software by Endress+Hauser enables reliable, secure measured data recording, electronic record management, batch report creation, archiving and transmission as specified in the FDA 21 CFR Part 11 and compliance with PMO and process authority requirements. Recorded data is stored on Memograph M RSG45 in internal memory (SD card) or on a removable USB memory stick. The standard 1 GB internal memory holds approximately 24 weeks of data when used as STLR/SFLR with one second recording interval. The FDM reporting software is installed on a local SQL server and connected to Memograph M RSG45 via LAN (EtherNet TCP/IP) for instant access to current and recorded data. Operators can enter annotations directly on the recorder or local server workstation. Records and annotations are available directly on Memograph M RSG45 for review and approval. The FDM provides a platform for supervisors, regulatory, quality, etc., to access records and annotations as well as workflow to approve and save records securely on company servers. Printing of records is available.

Typical applications are:
- Continuous pasteurization in HTST, UHT and aseptic
- ESL applications
- Juice pasteurization
- Egg pasteurization
- Cold product recording
- Product tank/silo temperature and level such as raw milk or aseptic tanks
- Clean-In-Place (CIP)
- Clean-Out-of-Place (COP)
- Retort, low acid
- General process recording and monitoring

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Compliance to the general requirements of FDA 21 CFR Part 11 (electronic records) and PMO

The recording system comprised of Memograph M RSG45 and FDM (Field Data Manager) software fulfills the general requirements of FDA 21 CFR part 11 related to system security, data traceability and integrity. Further details are laid out in the white paper: *Memograph M RSG45 and FDM FDA 21 CFR part 11 (supplement WP01028L)*.

Data integrity & system overview
The graphic data manager Memograph M RSG45 securely records, archives, stores and transmits all relevant information it reads from connected device(s): measured values are recorded, limit values are monitored and information is securely stored in the internal system memory.

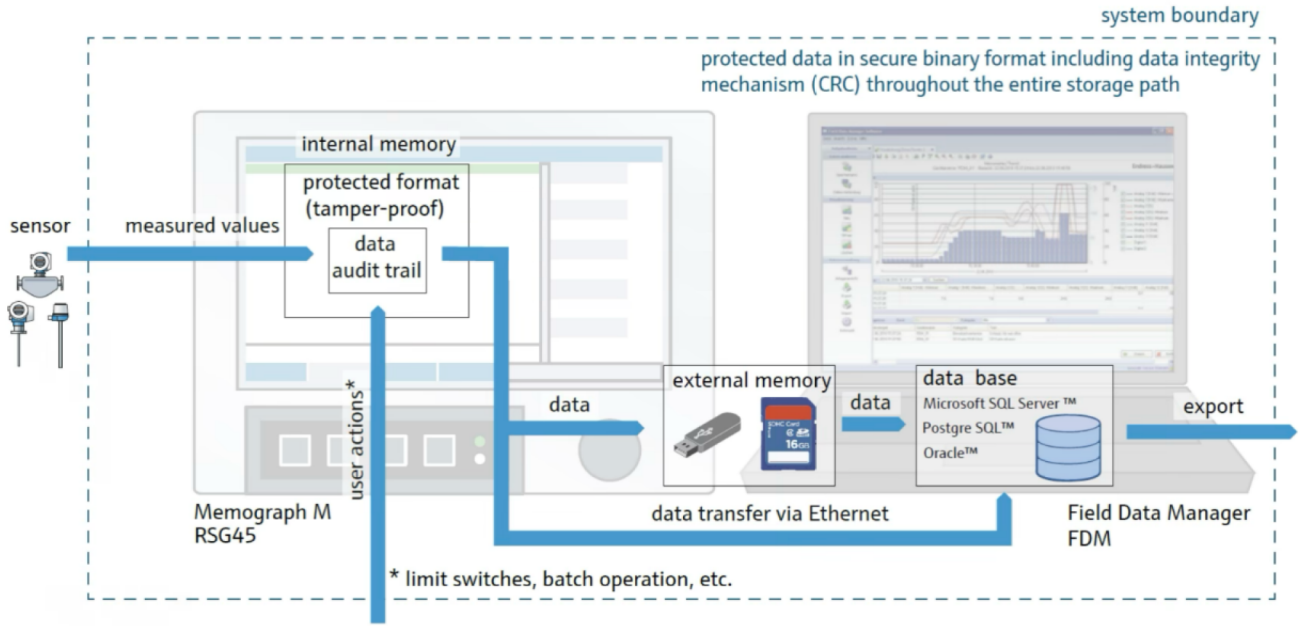

Figure 1: Data integrity from sensor to batch reporting

The data — as defined by measured values and electronic records of audit trail per FDA 21 CFR part 11 — is stored in a proprietary binary file format to protect against tampering. The integrity of the electronic records in the data manager is ensured by means of cyclic redundancy check (CRC). The CRC code is part of the raw data file.

Ordering, commissioning and operation of Memograph M RSG45 data manager and FDM software

1. Purchasing and scope of supply

1.1. Memograph M RSG45 order code ; recommended version for standardization RSG45-1W569/0

order option mandatory for PMO applications
order option allowed for PMO applications
order option not allowed for PMO applications

RSG45	-											+								
Option		10	20	30	40	50	60	70	80	90	100	110		500	550	560	570	580	600	610	895
010		**Approval:**																			
010	AA	Non-hazardous area																			
010	BK	ATEX II2G Ex px IIC, II2D Ex pD IIIC																			
020		**Power Supply:**																			
020	1	100-230VAC (+/-10%)																			
020	2	24V (-10%, +15%) AC/DC																			
030		**Slot 1:**																			
030	A	Not used																			
030	B	4x universal U,I,TC,RTD, pulse-/frequency input																			
030	C	4x HART/4...20mA input, HART transparency																			
040		**Slot 2:**																			
040	A	Not used																			
040	B	4x universal U,I,TC,RTD, pulse-/frequency input																			
040	C	4x HART/4...20mA input, HART transparency																			
050		**Slot 3:**																			
050	A	Not used																			
050	B	4x universal U,I,TC,RTD, pulse-/frequency input																			
050	C	4x HART/4...20mA input, HART transparency																			
060		**Slot 4:**																			
060	A	Not used																			
060	B	4x universal U,I,TC,RTD, pulse-/frequency input																			
060	C	4x HART/4...20mA input, HART transparency																			
070		**Slot 5:**																			
070	A	Not used																			
070	B	4x universal U,I,TC,RTD, pulse-/frequency input																			
070	C	4x HART/4...20mA input, HART transparency																			
070	D	Add. 8x digital input, 6x relay, 2x analog output																			
080		**Front Bezel:**																			
080	A	Zink diecast, powder-coated, light grey																			
080	B	Stainless steel, touchscreen,																			
080	C	DIN rail housing, no display																			
090		**Communication Master Functionality:**																			
090	1	Not selected																			
090	2	Modbus RTU/TCP, Master																			
100		**Communication Slave Functionality:**																			
100	A	Not selected																			
100	B	Modbus RTU/TCP, Slave,																			
100	C	PROFIBUS DP, Slave																			
100	D	PROFINET, IO-Device																			
100	E	EtherNet/IP Server																			
110		**Application Package:**																			
110	1	Not selected																			
110	2	Mathematic																			
110	3	Telealarm + mathematic																			
110	4	Batch software + mathematic																			
110	5	Waste water + storm overflow + telealarm + mathematic																			
110	6	Energy software (water + steam) + mathematic																			
110	7	Telealarm + energy software (water + steam + mathematic																			
110	9	Special version, TSP-no. to be spec.																			

500		**Operating Language Display:**
500	AA	English
500	AB	German
500	AC	French
500	AD	Spanish
500	AE	Italian
500	AF	Dutch
500	AG	Portuguese
500	AH	Polish
500	AI	Russian
500	AK	Chinese simplified
500	AL	Japanese
500	AR	Czech
500	AS	Chinese traditional
500	AT	Swedish
550		**Calibration:**
550	F1	Works calibration certificate
560		**Housing:**
560	GA	Terminal cover, Display housing
560	GB	Terminal cover, DIN rail housing
560	G1	Field, IP65, NEMA type 4 Encl.
560	G2	Desk top, cable with European two-pin earthed plug
560	G3	Desk top, cable with US plug
560	G4	Desk top, cable with Swiss plug
560	G9	Special version, TSP-no. to be spec.
570		**Service:**
570	HK	IQ/OQ Template + software backup
570	HL	IQ/OQ Template for fieldbuses + software backup
570	H8	Customized pre-configured
570	H9	Special version, TSP-no. to be spec.
600		**Licence Package FDM Software MS20:**
600	MA	Professional 1x workplace licence
610		**Accessory mounted:**
610	N1	SD card industrial grade, 1GB
895		**Marking:**
895	Z1	Tagging (TAG), metal
895	Z2	Tagging (TAG), on device
895	Z3	Commissioning label, paper
895	Z6	Tagging (TAG), by customer

Note: slot 5 option D must be selected if 2 x 4-20mA output is needed for retransmission. Option “D” Profinet or “E” EtherNet/IP in position 100 should be selected to retransmit measured values digitally to PLC. EtherNet/IP/PROFINET can be used for re-transmission of all inputs, outputs and states. EtherNet/IP is a protocol for cyclic data transfer to the PLC. EtherNet/IP/PROFINET are communication protocols purely for data exchange. Programming changes are not possible via these protocols. EtherNet/IP enables data transfer for measured values and digital inputs. Application-related setup device parameters can neither be written nor read by EtherNet/IP.

1.2. Software revision

The firmware revision for PMO applications is ENX200A 2.06.00 (bugfix index).
Memograph M RSG45 device including PMO specific firmware is ordered via option 570 Service “9 special version”, TSP no. 71704198.

For questions on ordering or any support regarding PMO applications, please contact:
Endress+Hasuer USA
2350 Endress Place
Greenwood, IN 46143
1-888-363-7377

1.3. Identification of device

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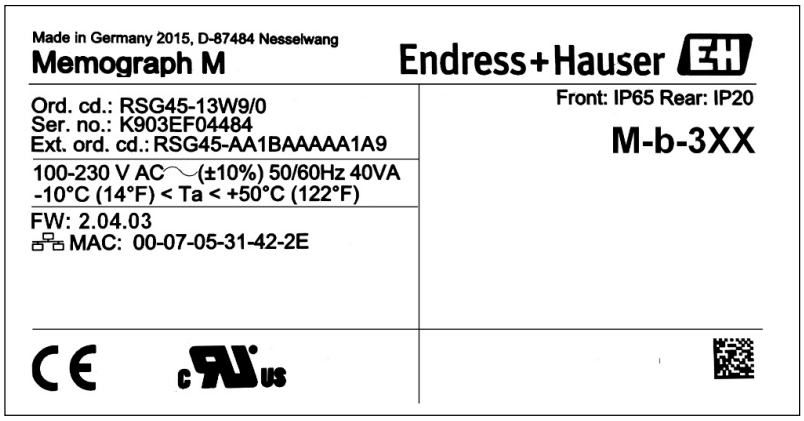
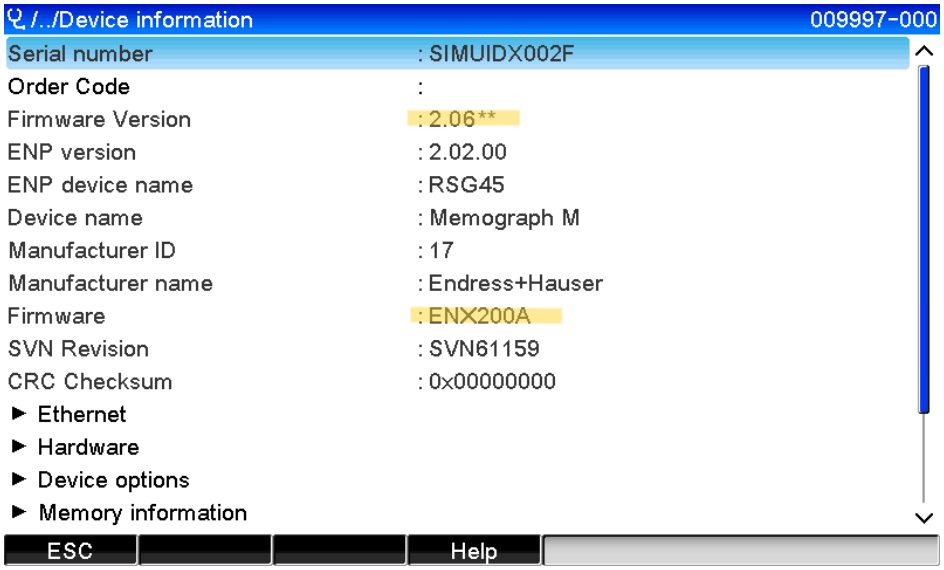
All device information like serial number, order code and firmware version are printed on the type plate of Memograph M RSG45. The device can be uniquely identified, and the ordering options can be compared with the options allowed for PMO applications. The M- b Memoranda index is printed on the type plate*.

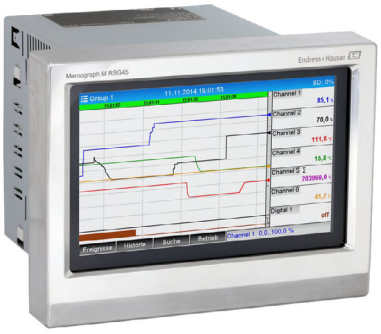


All device information can be displayed during operation by selecting:
Menu -> Diagnostics -> Device Information
The screen display with all information will appear as shown below.



1.4. Device housing

For PMO applications, Memograph M RSG45 with touch-screen display is used for easy operator interaction.



Stainless steel front with touch display

Operation, user logon, guidance and menu structure is easily accessible via the touch screen. A wired keyboard can be added for user convenience.

1.5. Visualization

What is visible on screen:
By utilizing signal groups, displayed and recorded values are defined by administrator during set-up. Any single or multiple values can be displayed on screen and up to 10 signal groups (screens) that are easily accessed manually by swiping left/right or set to automatically toggle on selectable time intervals. See examples in figures 1–4*. Check that the correct time and date are visible in the top bar and the padlock symbol is “locked” to ensure programming is disabled.

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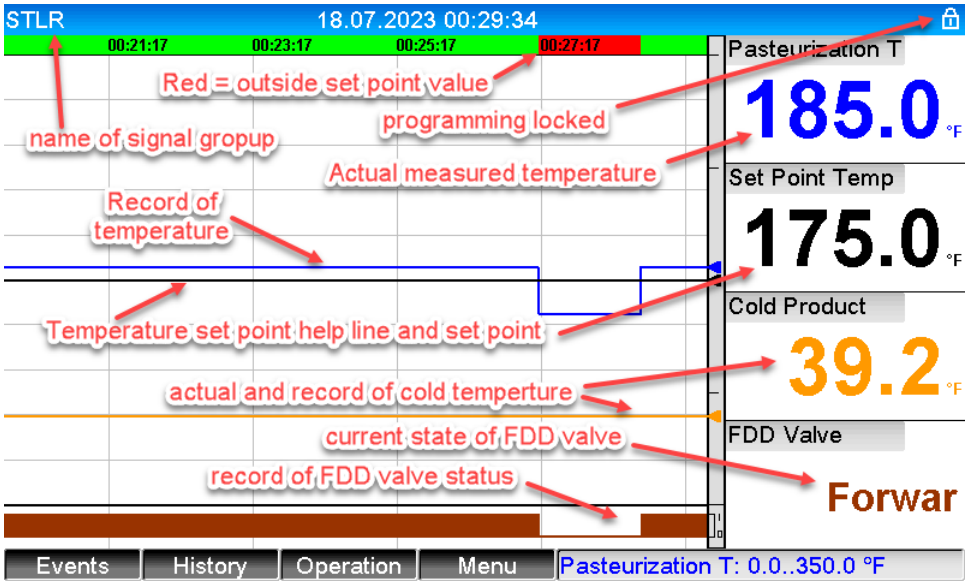


Figure 1: STLR (Safety Thermal Limit Record) screen

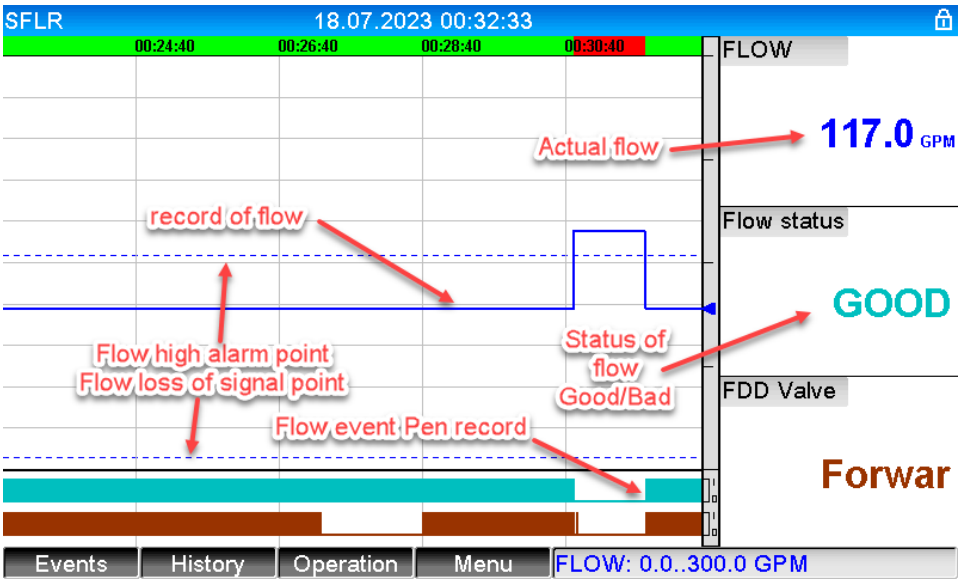


Figure 2: SFLR (Safety Flow Limit Record) screen

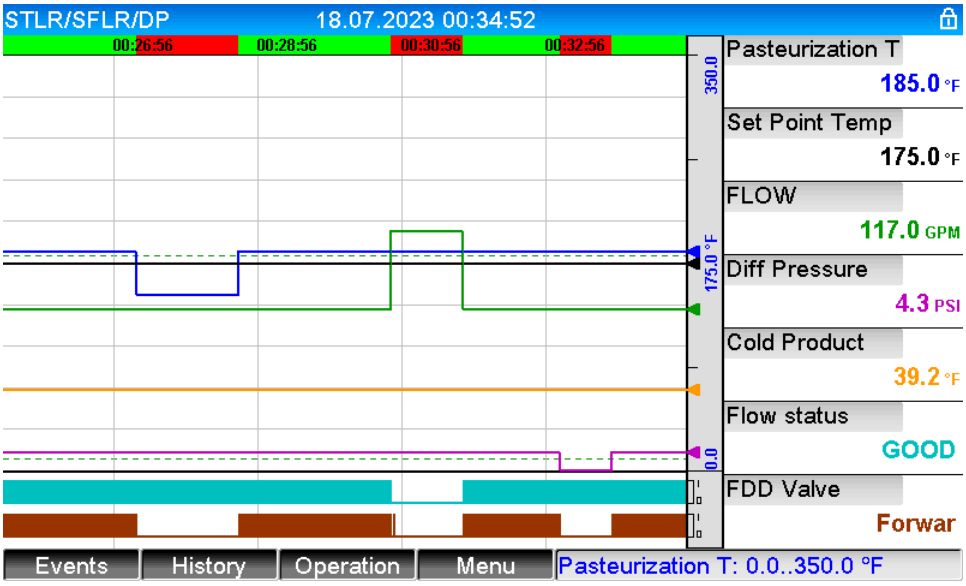


Figure 3: Combined screen with temperature, flow, differential pressure and cold product

Optional, Memograph M RSG45 can be used as a differential pressure switch (relay #5), and both sides and differential pressure are displayed. The recording is optional. A failure of pressure sensor (raw or pasteurized side) causes alarm condition and switching of fault relay (relay 4), which when wired in series with Relay 2 (temperature divert) will cause an immediate divert condition and capture in the event log.

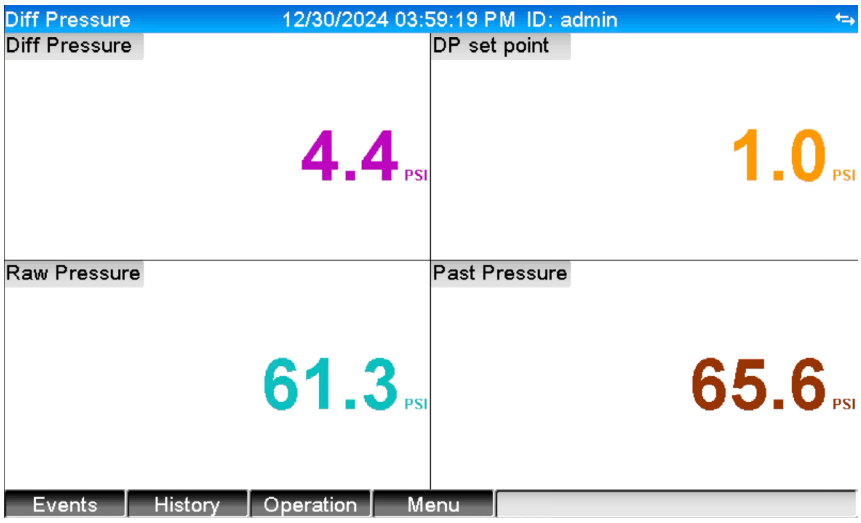
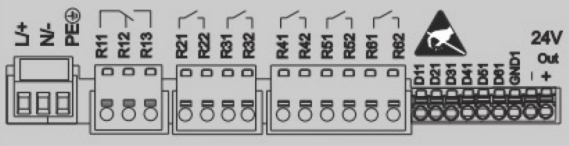


Figure 4: Differential pressure

1.6. Wiring instructions

Wiring of power supply, relay outputs and lock-out jumper

Type	Terminal			
	 A0019103			
Auxiliary voltage output, not stabilized, max. 250 mA			24V Out -	24V Out +
			- Ground	+ 24V (±15%)

If the auxiliary voltage is to be used for the digital inputs, the **24 V out -** terminal of the auxiliary voltage output must be connected with the **GND1** terminal.

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Figure 5: Power, digital inputs and relays*

Power supply terminal L/+ N/- (PE, ground)
Digital input 1 (D11) –PMO required lock out jumper to see figure 6
Digital input 2 (D21) - FDD valve feedback signal see figure 5
Digital input 3 (D31) - not used
Digital input 4 (D41) - optional flow totalizer start/stop/reset) see figure 5
Digital input 5 (D51) - optional CIP on/off see figure 5
Digital input 6-14 - not used

Relay 1 – not used
Relay 2 (R21/R22) – output contact for temperature set point (set to closing)
Relay 3 R31/32 – flow (loss of flow+high flow alarm (Inband function) (set to closing)
Relay 4 R41/R42 – system or sensor fault (set to opening). Relay #4 must be wired in series with Relay #2 for divert at system fault
Relay 5 R51/R52 – differential pressure switch (if used) (set to opening)
Six additional relays can be ordered in slot 5 if required for a total of 12 relays

Ground (-) bridge -> black wire
Protection jumper (+) to D11 -> white wire

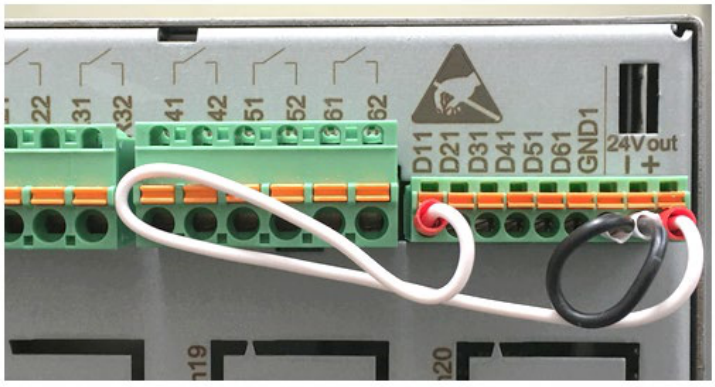

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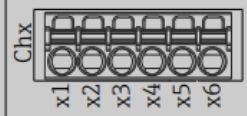
Figure 6: Lock out jumper - connect jumper between terminal – and GND and + **this jumper must be in place during operations and disconnected to allow program changes***

Wiring of inputs (up 20 analog inputs in 5 slots with 4 channels each)

Type	Terminal					
						
	x1	**x2**	**x3**	**x4**	**x5**	**x6**
Current/pulse/frequency input [1)]					(+)	(-)
Voltage > 1V		(+)				(-)
Voltage ≤ 1V				(+)		(-)
Resistance thermometer RTD (2-wire)	(A)					(B)
Resistance thermometer RTD (3-wire)	(A)			b (sense)		(B)
Resistance thermometer RTD (4-wire)	(A)		a (sense)	b (sense)		(B)
Thermocouples TC				(+)		(-)

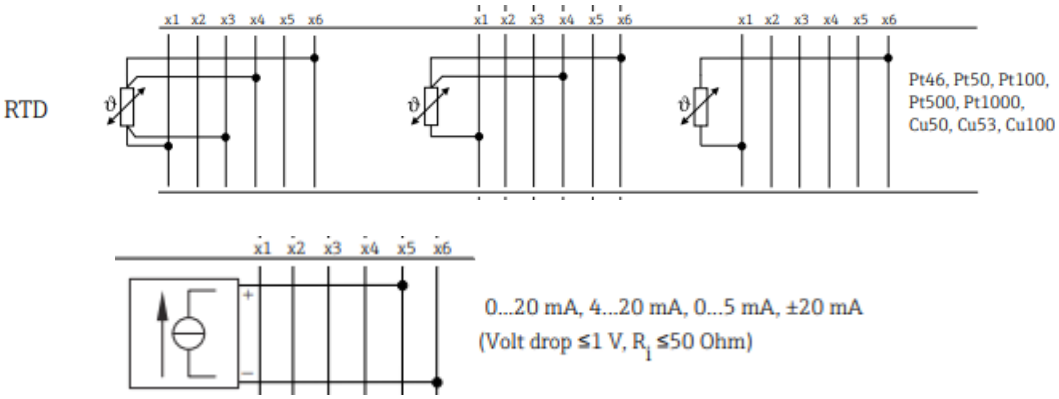


Figure 7: Input wiring
Ch 1 – 4-wire RTD or 4-20mA from hold tube (hot product) ensure use of shielded cable
Ch 2 – 4-20mA from magnetic flowmeter (flow velocity) (SFLR)
Ch 3 – 4 wire RTD or 4-20mA from cold product sensor
Ch 4 – 4-20mA from pasteurized side pressure sensor (if used)
Ch 5 – 4-20mA from raw side pressure sensor (if used)

Wiring of 2 x 4-20mA re-transmission outputs, optional slot 5 card must be installed.

Type	Terminal			
				
Analog output 1-2	**O15**	**O16**	**O25**	**O26**
	Analog output 1 (+)	Ground, analog output 1 (-)	Analog output 2 (+)	Ground, analog output 2 (-)

Figure 9: 4-20mA Re-transmission

Optional output card in slot 5 must be installed. Default: Analog output 1 (Hot Product) and Analog output 2 flow rate (values for re-transmission) preference can be changed in programming.

Re-transmission of values via EtherNet/IP
All measured variables and digital inputs alarms can be retransmitted via EtherNet/IP or PROFINET slave functions. Option D or E must be selected in order structure for availability of functionality. EtherNet/IP is a protocol for cyclic data transfer to the PLC. EtherNet/IP/PROFINET are communication protocols purely for data exchange. Programming changes are not possible via these protocols.

2. Commissioning

The following instructions describe the settings that must be made for PMO applications.
For the general setup and further details of Memograph M RSG45 please refer to Memograph M RSG45 user manual. See www.us.endress.com.

Note, some screenshots below are from Memograph M RSG45 screen, and we recommend using: the web server for faster and easier commissioning as well as saving and up/downloading of programs. Menu terminology and location is identical when using web server—see screenshot of web server interface and recorder screen.

Setup via web server
To configure the device via the web server, connect the device to a PC via Ethernet (or Ethernet over USB). Please observe the information and communication settings for Ethernet (or Ethernet over USB) and the web server under → 🖹 43.

To configure the device via a web server, Administrator or Service authentication is required. ID and password administration is performed in the main menu under “Setup -> Advanced setup -> Communication -> Ethernet -> Configuration web server -> Authentication.”
ID default value: admin; password: admin
Note: The password should be changed during commissioning.

If security settings are according to “FDA 21 CFR Part 11,” you must have Administrator rights to configure the device via a web server.

Establishing a connection and setup
Procedure for setting up a connection:
1. Connect the device to the PC via Ethernet (or Ethernet over USB).
2. Start the browser on the PC; enter the IP address: http://<IP address> to open the web server for the device. Note: Leading zeros in IP addresses must not be entered (e.g. enter 192.168.1.11 instead of 192.168.001.011).
3. Enter the ID and password, and confirm each by clicking “OK” (see also the “web server” section of the Operating Instructions → 🖹 64)
4. The web server shows the instantaneous value display of the device. In the web server taskbar, click “Menu -> Setup -> Advanced setup.”
5. Start the configuration.

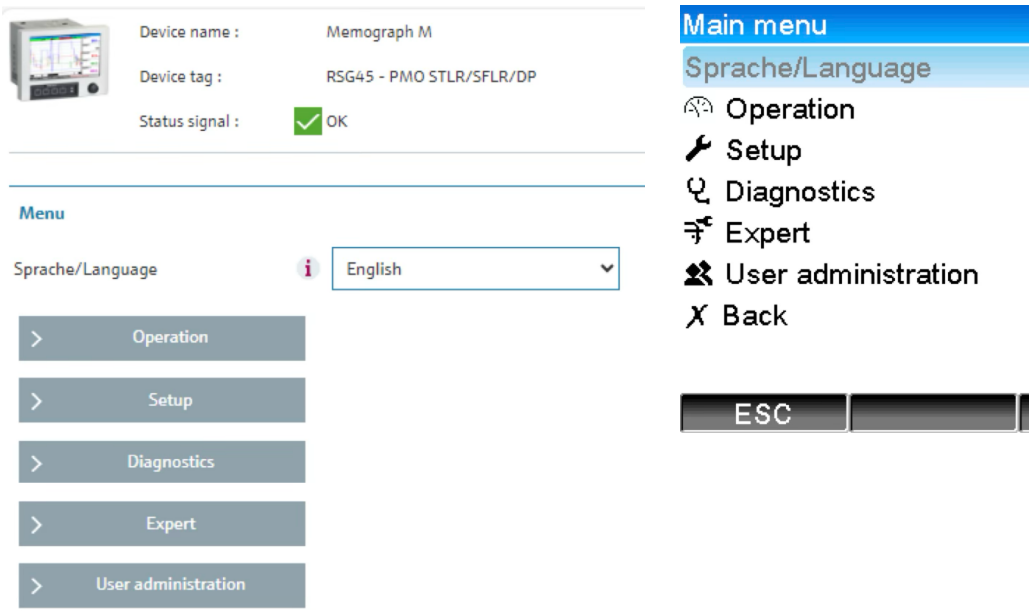


Figure 10: Web server and touch-screen interface for set-up

2.1. User administration according to FDA 21 CFR Part 11

For PMO applications, it is mandatory to use the user administration according to FDA 21 CFR Part 11, which is implemented in Memograph M RSG45.

Memograph M RSG45 manages 50 user accounts in five authorization levels (administrator, main user, operator 1/2/3) and assigns access rights for the respective accounts. For PMO applications, the only user roles that will be used are “Admin” and “Main User”. We recommend two or more individuals with “admin” rights. Main users can be added/deleted without breaking regulatory seal. FDA user roles and access authorization:

User administration and authorization in compliance with FDA 21 CFR Part 11

	Admin	Main user	Operator Level 1	Operator Level 2	Operator Level 3
Setup change	yes	no	no	no	no
Limit (Set point) change	yes	yes	no	no	no
Post protocol	yes	yes	yes	no	no
Quit messages	yes	yes	yes	yes	no

Figure 11: FDA user roles and access authorization

Setup change: change the parameter settings for Memograph M RSG45, for units with regulatory seal installed, the seal must be broken to make programming changes and lock jumper removed. See Figure 6 under “wiring”

Limit (set-point): the set-point values are defined and entered in admin mode only. In main user mode, only predetermined set point values can be selected by operator. For PMO this is e.g. the divert set-point temperature

Post protocol: subsequent text entries during or at the end of production batches

Quit messages: confirming of error messages.

2.1.1 Activation of FDA user administration

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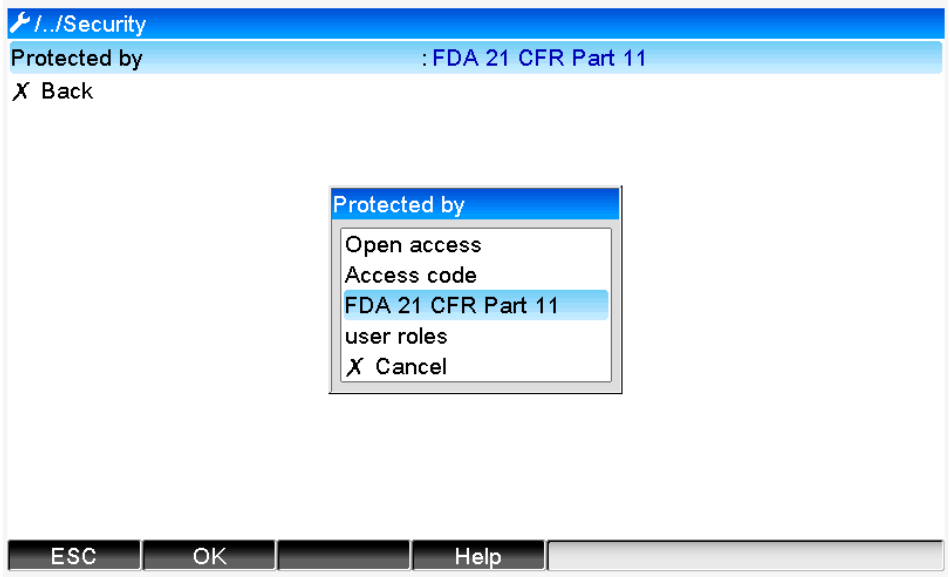
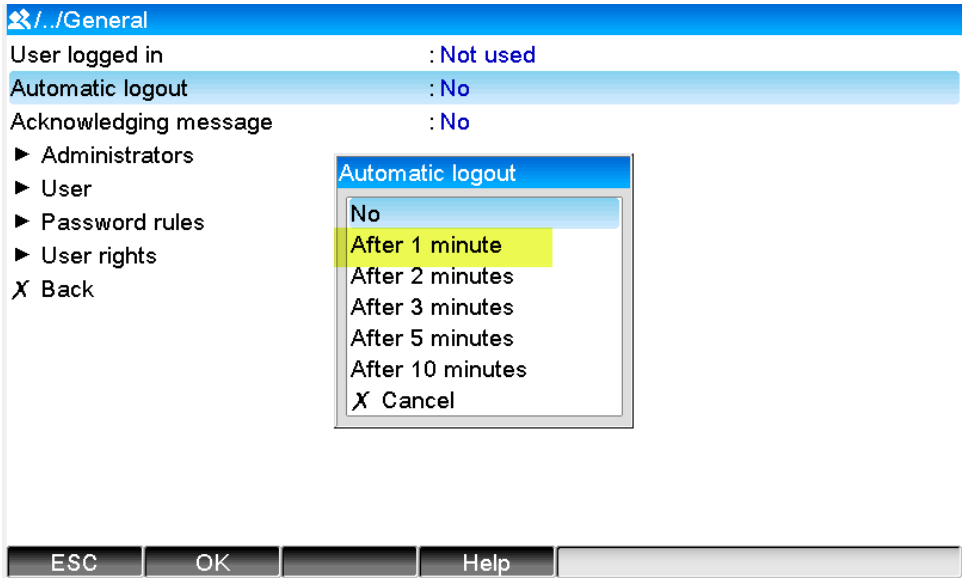
Select the setting for ***FDA 21 CFR Part 11*** administration under*:
Menu -> Setup -> Advanced setup -> System -> Security -> Protected by

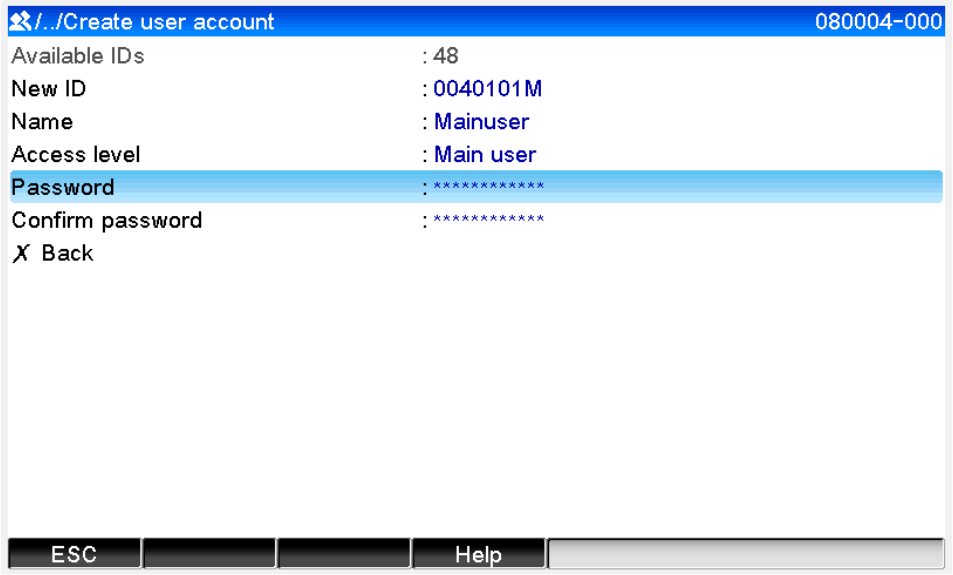


2.1.2 Creation of user accounts and assigning of rights

Step 1: Set up the general FDA administration settings like password rules, log-off times, etc. We recommend no more than five minutes as the automatic logout.
Menu -> User administration -> General

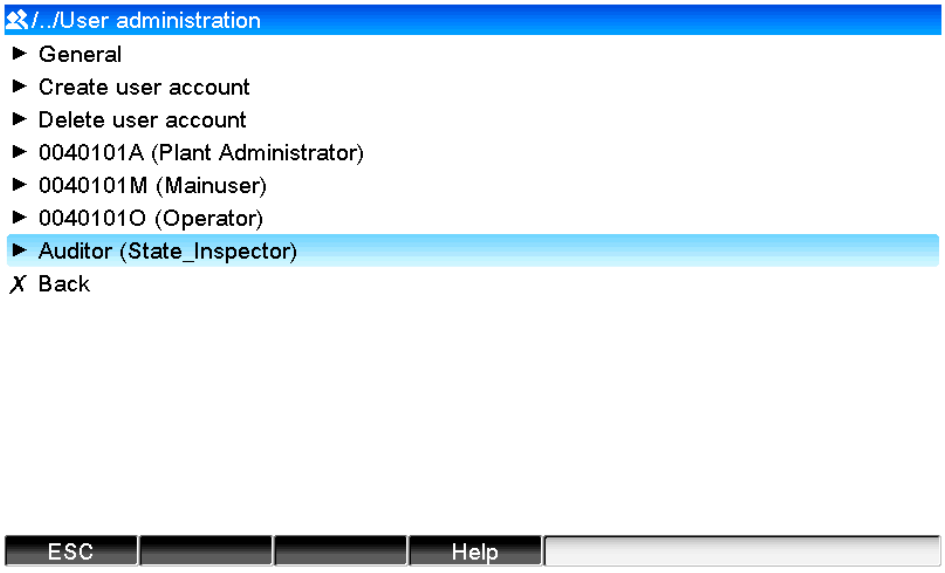


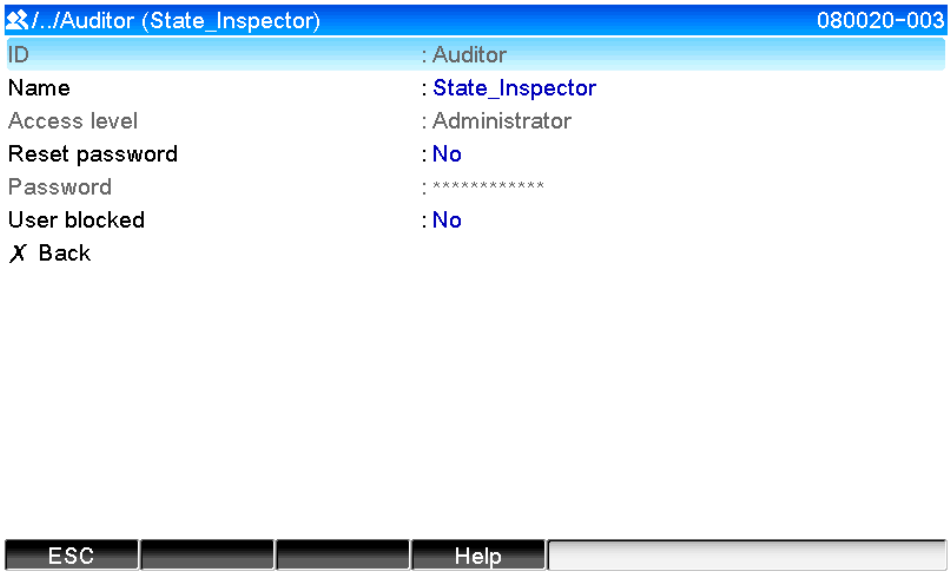
Step 2: Create all user accounts with ID, name, access level and password
Menu -> User administration -> Create user account -> New ID
Important: Once the FDA administration is activated, only the admin can manage user accounts. If the username /password of the admin is lost, a hard reset code from the factory is required for any administration or setup changes. All data/settings will be lost—make sure to remember login credentials.



Example: FDA user role main user
Example: overview all created accounts

Remark: To give a state inspector (as an auditor) access to the system and check all parameter setup settings, the plant administrator should create login credentials for state/FDA inspectors (auditor) (see screenshot above) with an initial password. At the first audit of the system, the auditor should change the initial password to a personal password.

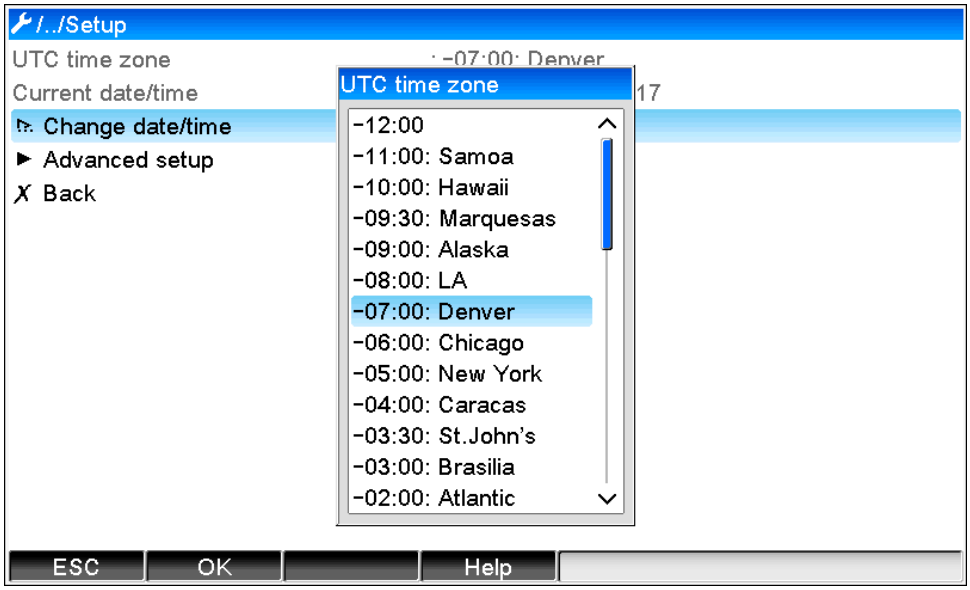




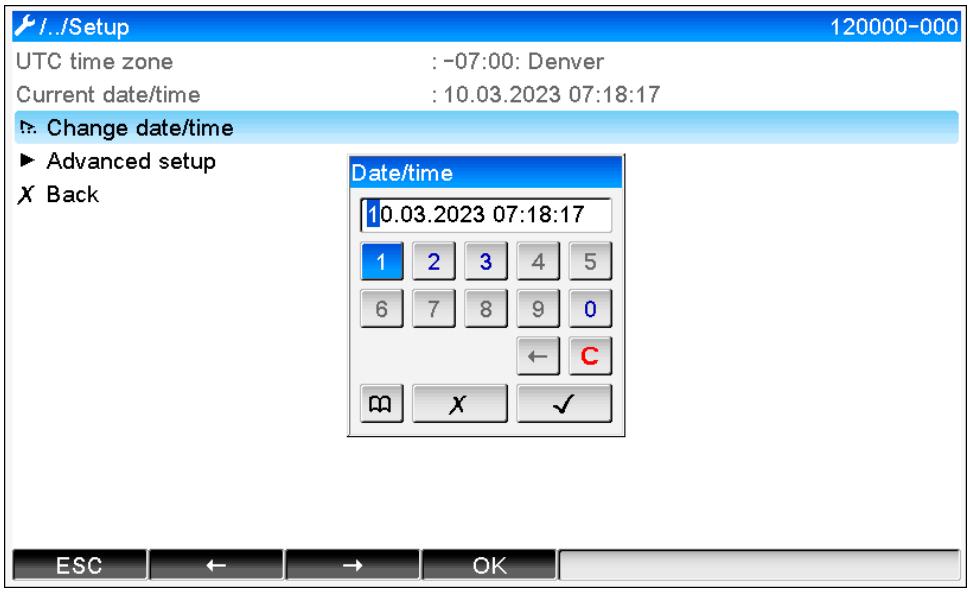
2.1.3 Set up of real-time clock

All data records (measured values, operator inputs, events, etc.) are signed with a unique timestamp by activating the integrated real-time clock. In conjunction with the operator authentication, a complete and non-tamperable audit trail is created in accordance with the requirements of FDA 21 CFR part 11.

To set up the real-time clock, please proceed as follows:
Menu -> Setup -> Change date/time

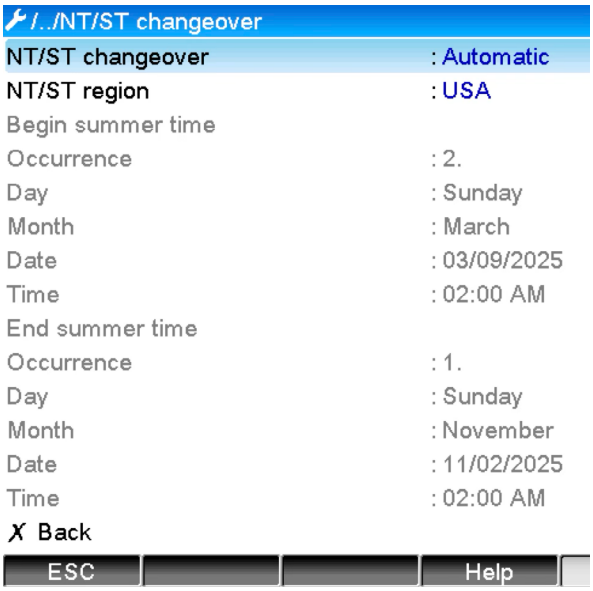


Select the local time zone



Adjust date/time details if necessary

Daylight Saving Time (DST)
Memograph M RSG45 automatically swiches to Daylight Saving Time when set up for automatic change over. This ensures that the recorder skips/adds an hour for recording automatically during the change, thus ensuring that no data is lost.
Menu -> Setup -> advanced setup-> system->date/time setup->NT/ST changeover-> automatic



2.2 Safety Temperature Limit Recorder (STLR)

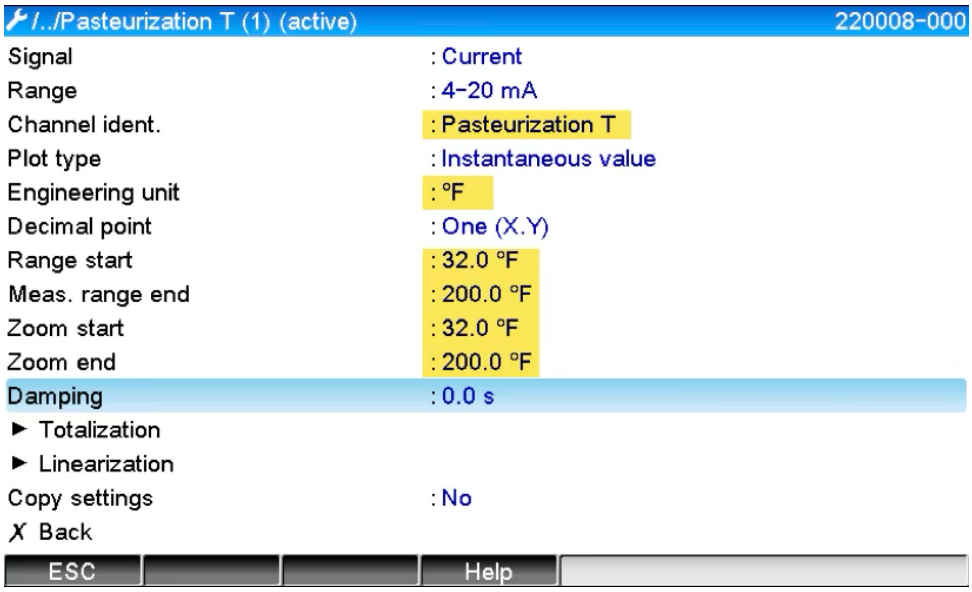
For PMO compliant application as an STLR, the device parameter should be set up as described in the following chapters below.

2.2.1 Example set up for a temperature measurement value

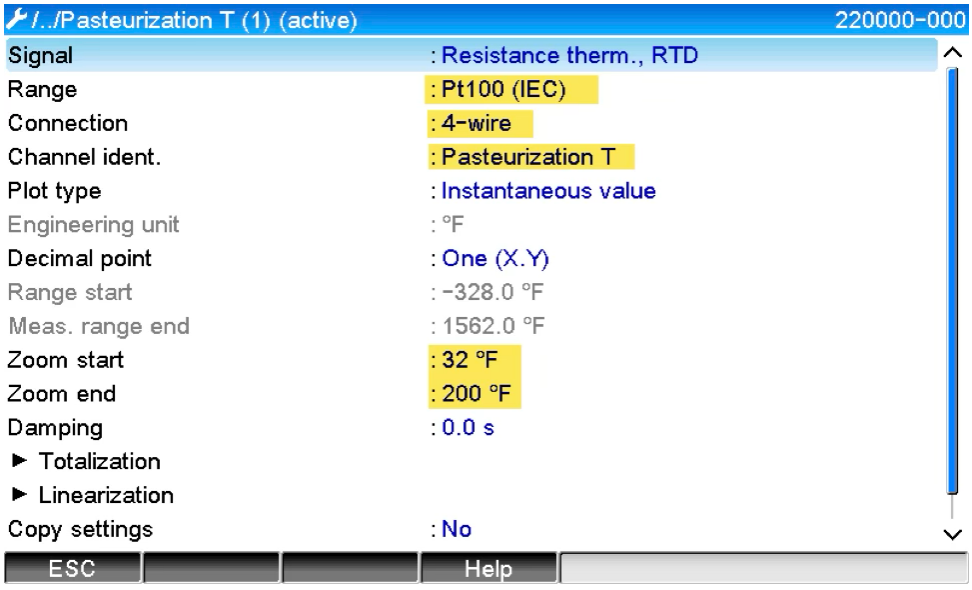
*Pasteurized Milk Ordinance required

Values highlighted in yellow will or may need to be adjusted based on local application needs. To record a measured temperature value, please proceed as follows*:
Menu -> Setup -> Advanced setup -> Inputs -> Universal inputs -> Add input

Select physical input by channel #1, set up channel name (e.g. Pasteurization T), define measurement and display range, etc. For all details, please refer to Memograph M RSG45 operating manual. Temperature sensors for PMO applications can be analog 4-20mA sensors or 3/4-wire RTD sensors. See example configurations below.



Example: setup of 4-20mA analog temperature sensor; note: damping must be set to 0 seconds



Example: setup of 4-wire RTD analog temperature sensor; note: damping must be set to 0 seconds

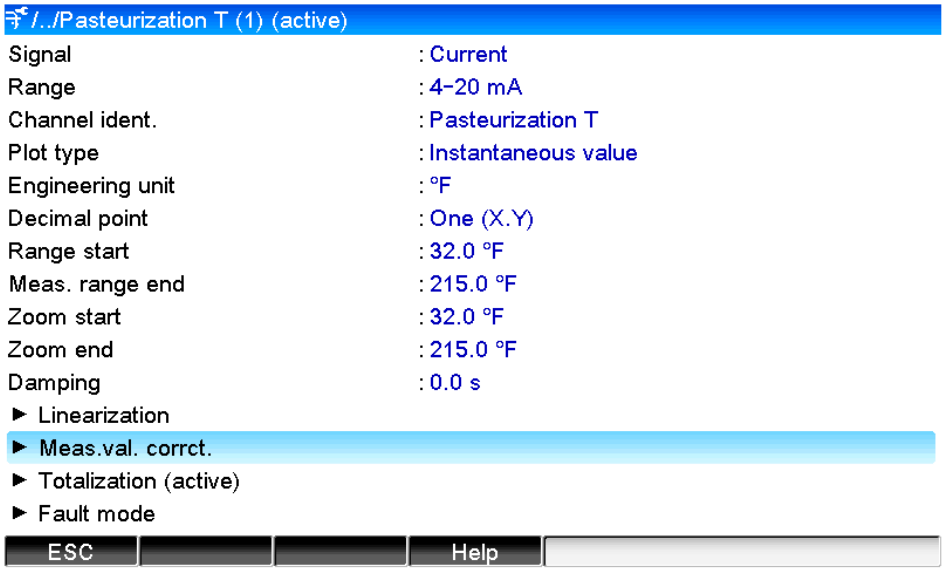
2.2.2 Temperature offset

*Pasteurized Milk Ordinance required

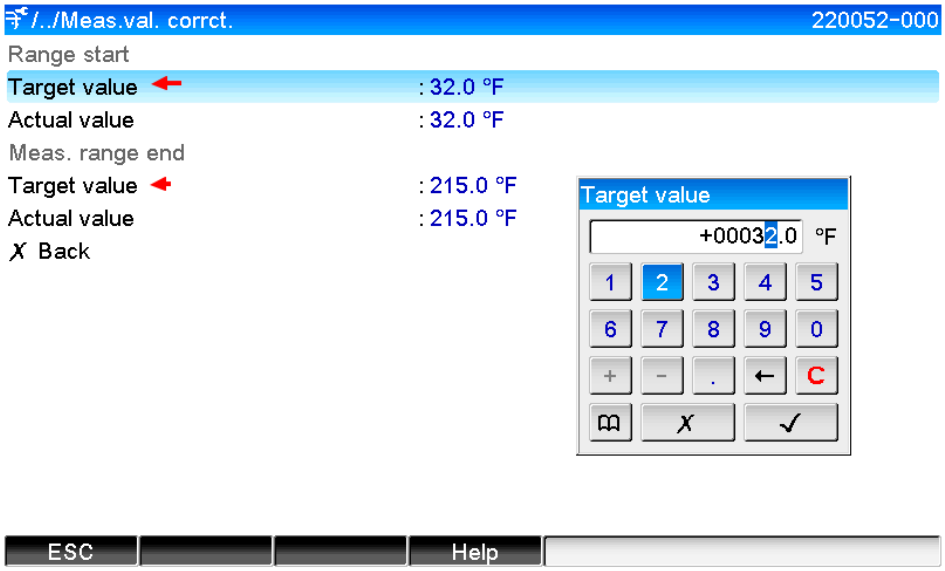
To ensure compliance of the recording thermometer reading versus the indicating thermometer reading (DRT), an offset can be entered. The configuration for 4- 20mA and RTD sensors is slightly different*.

For 4-20mA sensors, please proceed as follows:
Menu -> Expert -> Inputs -> Universal inputs-> select the temperature (4-20mA) sensor

Select ***"Meas.val.corrct."***



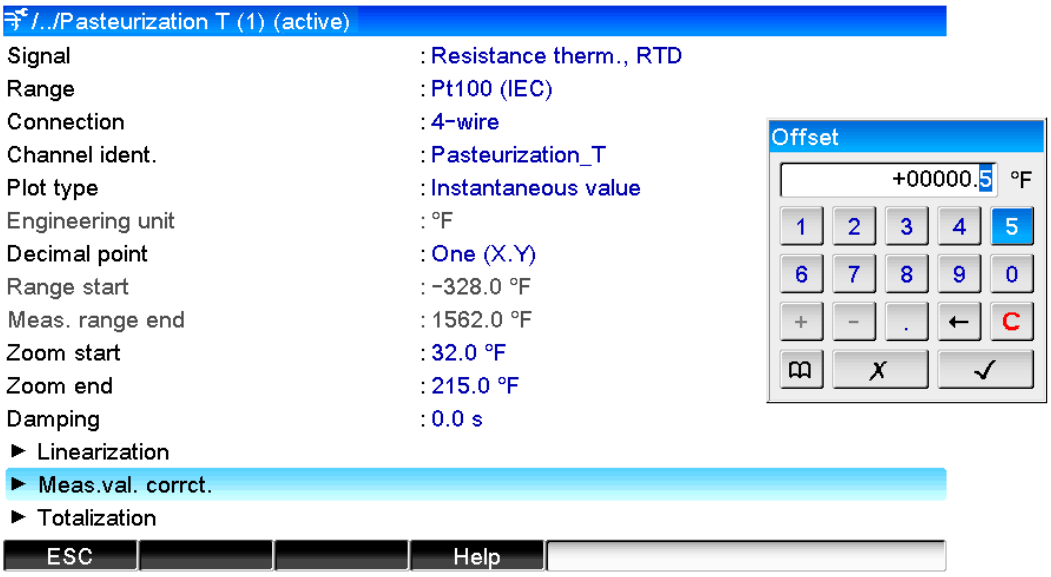
The target values entered should be the same delta versus the respective actual values. This will ensure a constant offset across the entire 4-20 mA range.



Remark: offset correction is an expert parameter which can only be done by a plant administrator when setup lock jumper is removed

For RTD sensors, please proceed as follows:
Menu -> Expert -> Inputs -> Universal inputs -> select the temperature (RTD) sensor

Select ***"Meas.val.corrct."*** Enter a value with the indicated offset

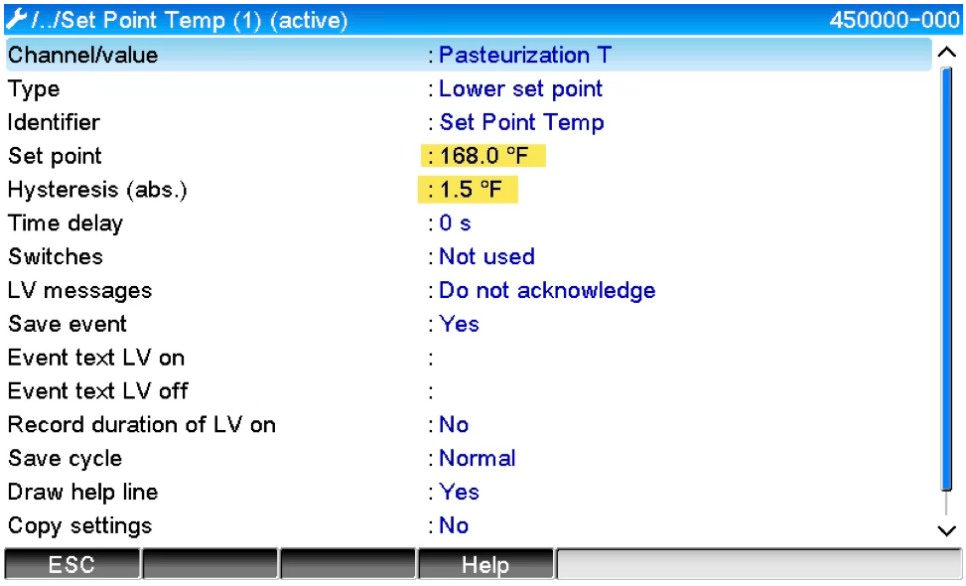


2.2.3 Limit switches (divert set-point) for temperature measurement

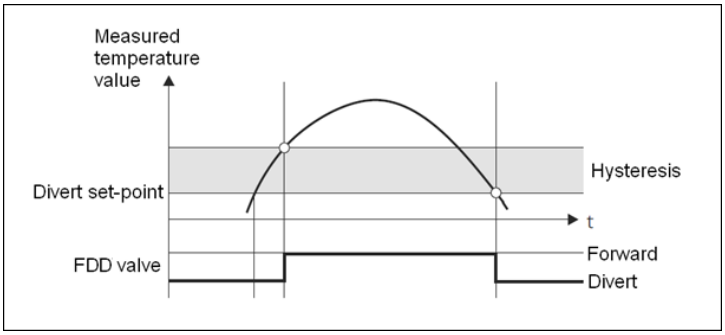
*Pasteurized Milk Ordinance required

Monitoring the process temperature is the most important aspect in heat treatment process applications. The measured value can be monitored with limit values. Limit value violations are logged in the audit trail and displayed in the recording. Setting up a divert set-point temperature for a measuring channel*:

Menu -> Setup -> Advanced setup -> Application -> Limits -> Add limit value



A positive hysteresis of up to 1.5 °F can be applied to divert set-point value monitoring. If the temperature is exceeded, the FDD-valve is switched according to the picture below. If the measured temperature falls below the divert set-point, this is done immediately. All relays should be set to “opening” to ensure failsafe mode in case of power failure or other errors.



Programming vs operating mode

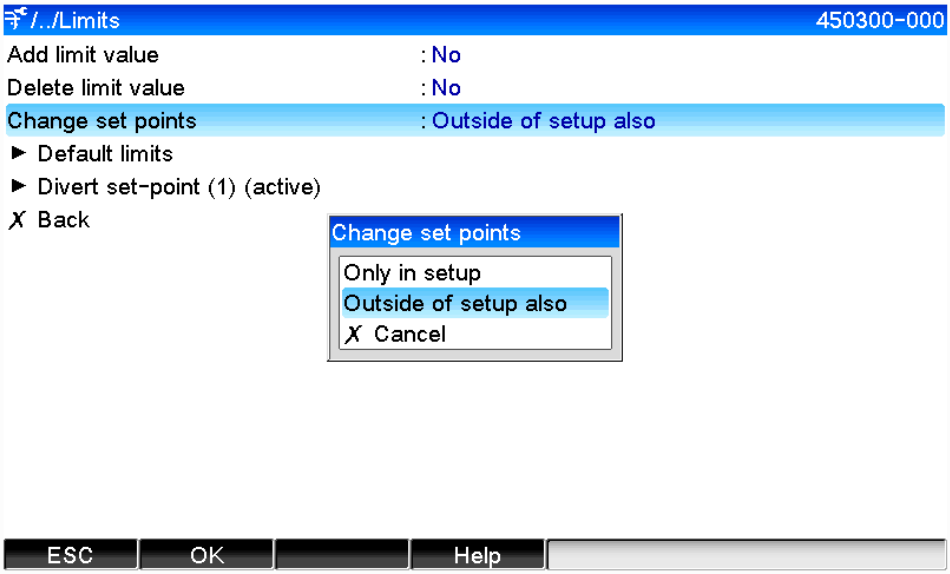
*Pasteurized Milk Ordinance required

To switch relay #2 indicating the divert set-point temperature has been met to the public health controller, the following two math channels’ logic need to be set to ensure that forward flow is not possible in unlocked (programming mode)*.

/../OperatingMode (6) (active)	400000-005
Function	: Formula editor
Channel ident.	: OperatingMode
Formula	: and(DI(2;1)=1;LMT(2;1)=0)
The result is	: State
Switches relay	: Relay 2
Description `H`	: run
Description `L`	: progr
Save event	: Yes
Event Message	: Do not acknowledge
Event text L->H	: Run Mode on
Event text H->L	: Program Mode on
Record duration	: No
Copy settings	: No
✗ Back	

ESC | Help

Important: to give the operator the ability to select a divert set-point from the pre-programmed list, activate the access as follows:
Menu -> Expert -> Application -> Limits-> Change set points -> "Outside of setup also"

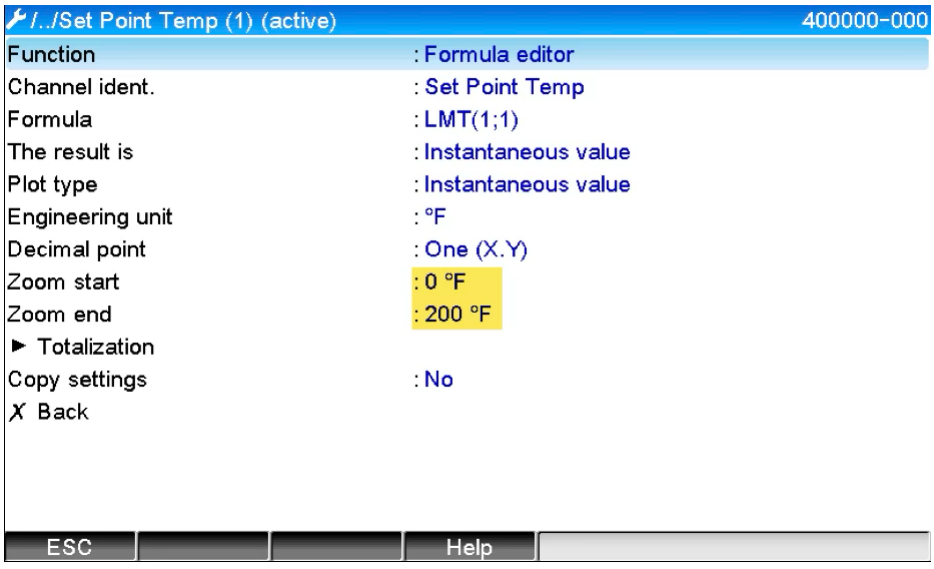


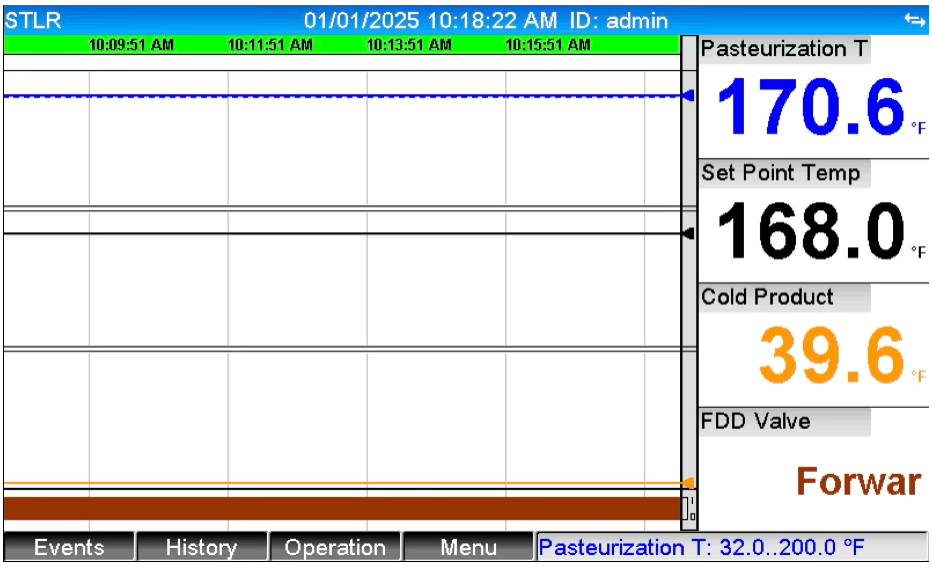
2.2.4 Draw line for divert set-point for temperature measurement

To visualize the actual divert set-point temperature on the main screen, a mathematic function can be used.

Input example to set up a draw line for limit switch , e.g. Pasteurization_T:
Menu -> Setup -> Advanced setup -> Application -> Maths

The formula LMT(1;1) assigns the set point (1) to the channel identifier ***Set-point Temp***. This value will be displayed as draw line.



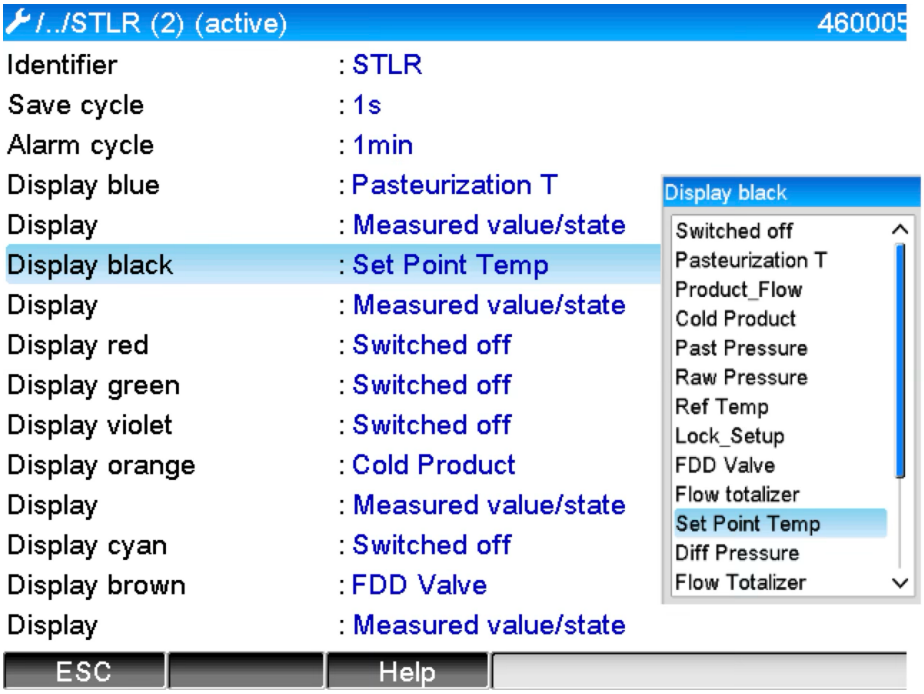


The draw line will be displayed in the analysis software “FDM Field Data Manager” in the same way. The example above shows a set-point of 168°F. Any selection of a set-point (e.g. for a new batch) executed by an operator is documented tamper-proof with ID; username and timestamp according to FDA 21 CFR Part 11 in the audit-trail.

2.2.5 Visualization

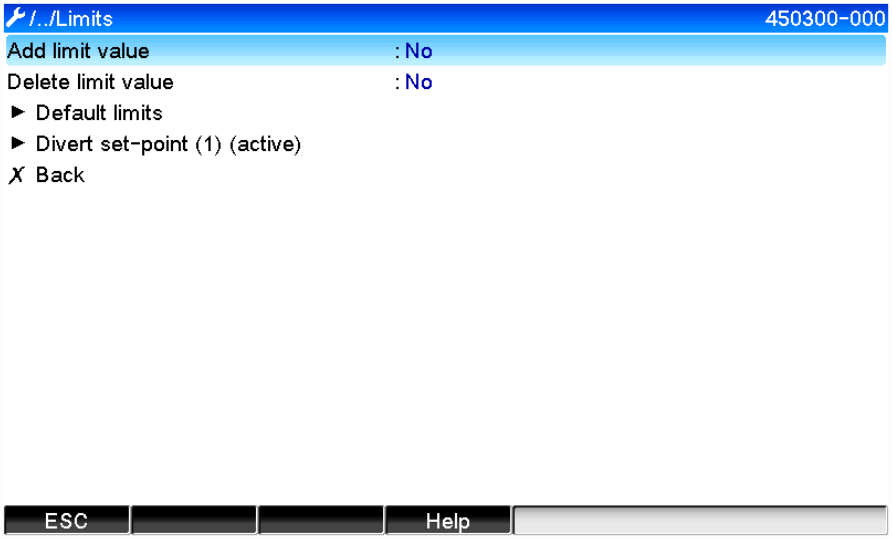
To visualize the measured temperature, divert set-point temperature and FDD valve state, proceed as follows and assign the measures to the colors as shown in the screenshot below.

Menu -> Setup -> Advanced setup -> Application -> Signal groups -> Group 1



2.2.6 Predefined divert set-point temperatures (Default limits)

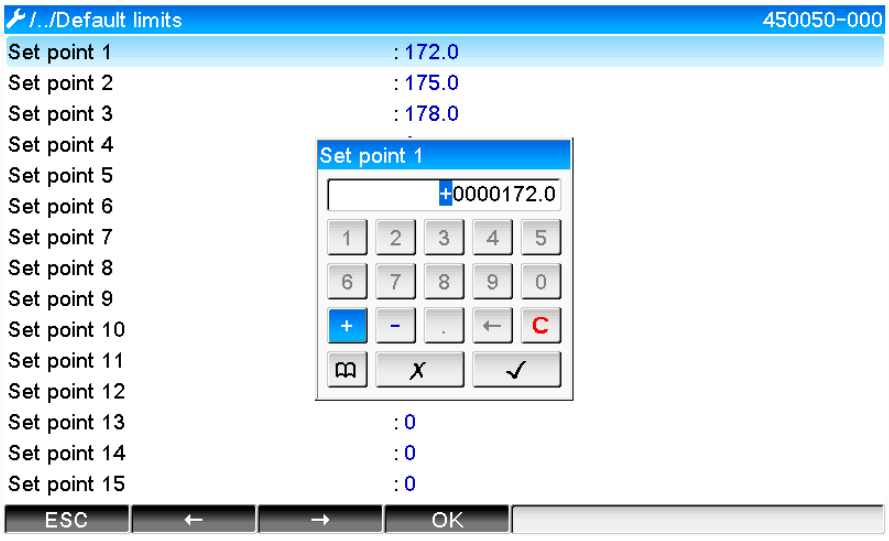
The divert set-point temperature, which can be selected by a “main user” during operation of a batch, must be predefined by the plant administrator during set-up and prior to sealing unit. This prevents the main user from entering impermissible values for the divert set-point temperature. The system administrator can enter up to 20 standard limit values in a list. To edit the list, the administrator must be logged in and edit the values according to the following path:
Menu -> Setup -> Advanced setup -> Application -> Limits -> Default limits



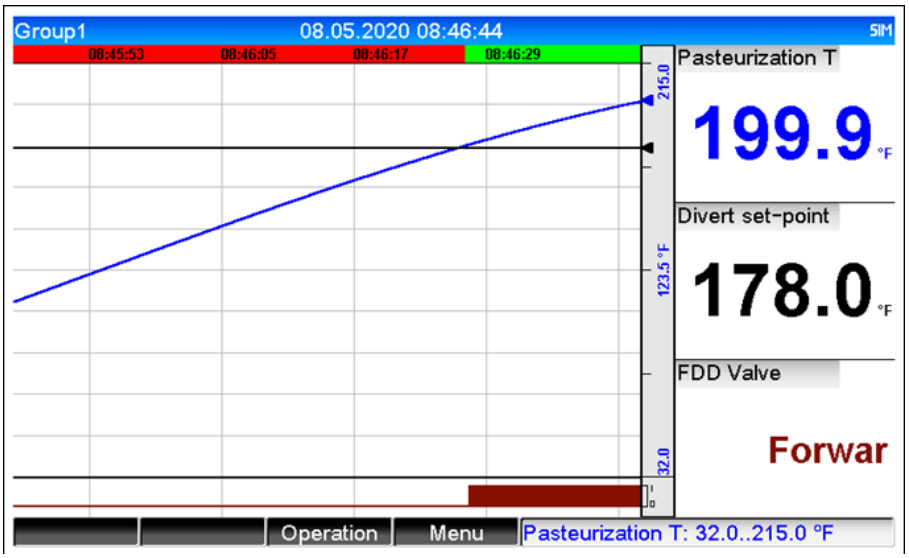
A temperature value can be assigned to each of the 20 list entries

2.2.7 FDD (flow diversion valve) status indication

To indicate the FDD valve status, configure a digital input #2 (where the FDD valve status signal is wired) as a control input like shown below. ***Menu -> Setup -> Advanced setup -> Inputs -> Digital inputs -> Add input***

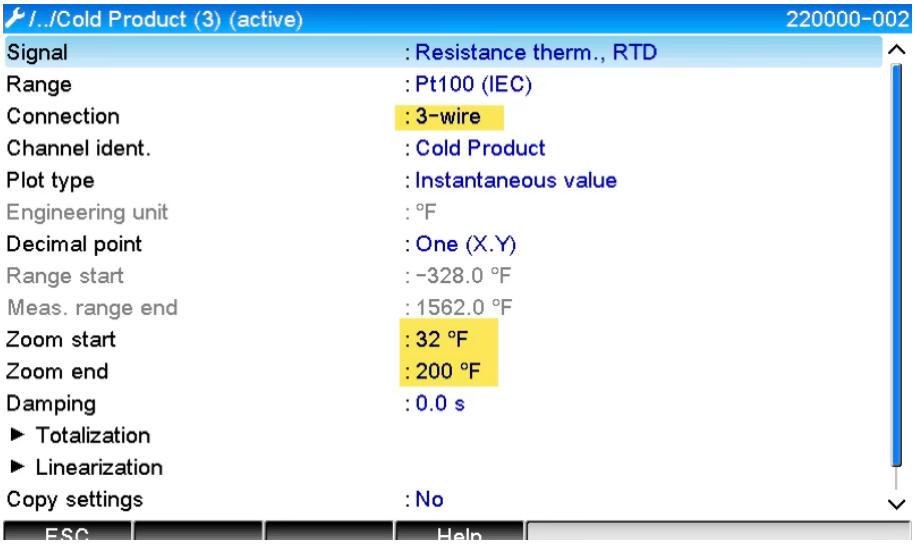


Visualize the status in the signal group. Display will be similar to the below:



2.2.8 Display of cold product temperature (optional)

An optional temperature sensor can be connected to input channel #3 and set up to display the cold product temperature.

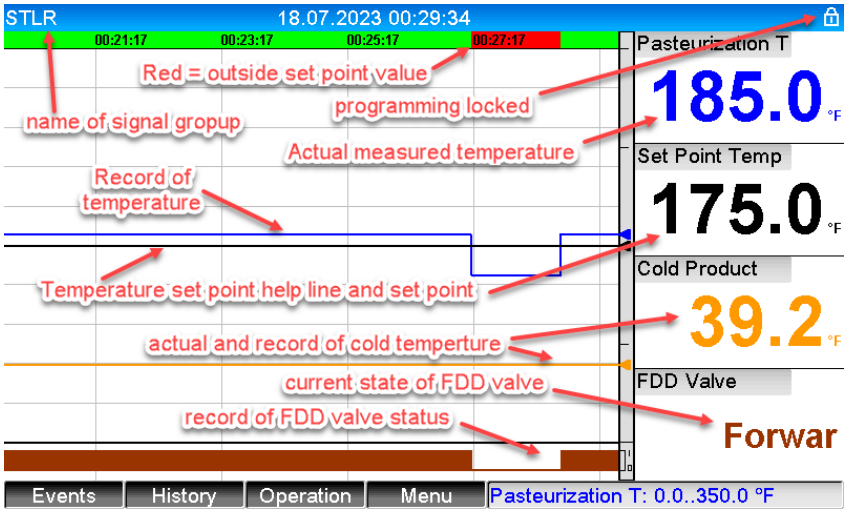


Example: parameter setting of an optional cold product temperature sensor
Note: damping must be set to 0 seconds

2.2.9 STLR visualization

*Pasteurized Milk Ordinance required

After completing the set up, the visualization will display the information as shown below*:



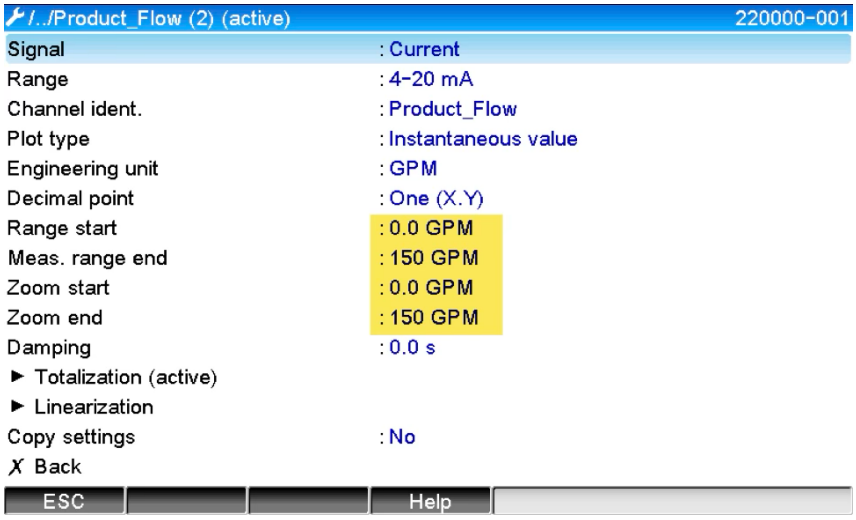
2.3 Safety Flow Limit Recorder (SFLR)

In addition to monitoring the temperature signal as a Safety Thermal Limit Recorder (STLR), Memograph M RSG45 data manager can take over the functionality of the Safety Flow Limit Recorder (SFLR) in the same device. The basic task is to monitor and record the (product) flow rate and to output and document the “high flow alarm” and the alarm for low flow (loss of signal). This is generally 60% of range and 5% of range.

2.3.1 Configuration of flow monitoring

*Pasteurized Milk Ordinance required

To record and monitor the flow value, please proceed as follows*:
Menu -> Setup -> Advanced setup -> Inputs -> Universal inputs -> Add input
Select physical input channel 2, set up channel name (e.g. Flow), select unit GPM and measurement range 0 to XXX GPM. The maximum value XXX for the flow corresponds to the 20mA signal which equals to the calibrated signal of the flow sensor. In the example for the screenshots, a maximum flow rate of 150 GPM was chosen.

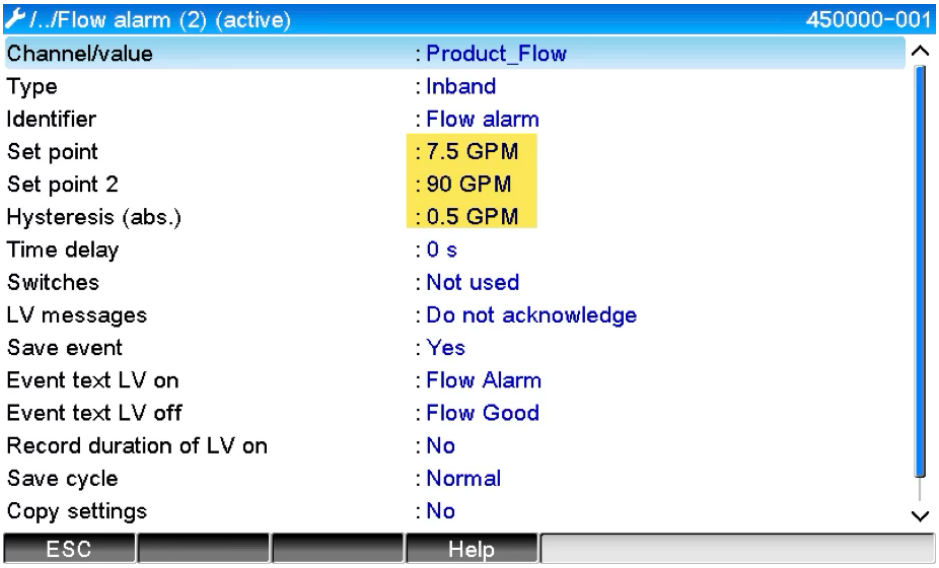


The measured flow value is recorded and the trigger limit switch for high flow alarm and low flow (loss of signal). These limit value violations are logged in the audit trail and displayed in the recording.

2.3.2 Setting up the alarm limit(s) for flow (loss of signal and high flow)

*Pasteurized Milk Ordinance required

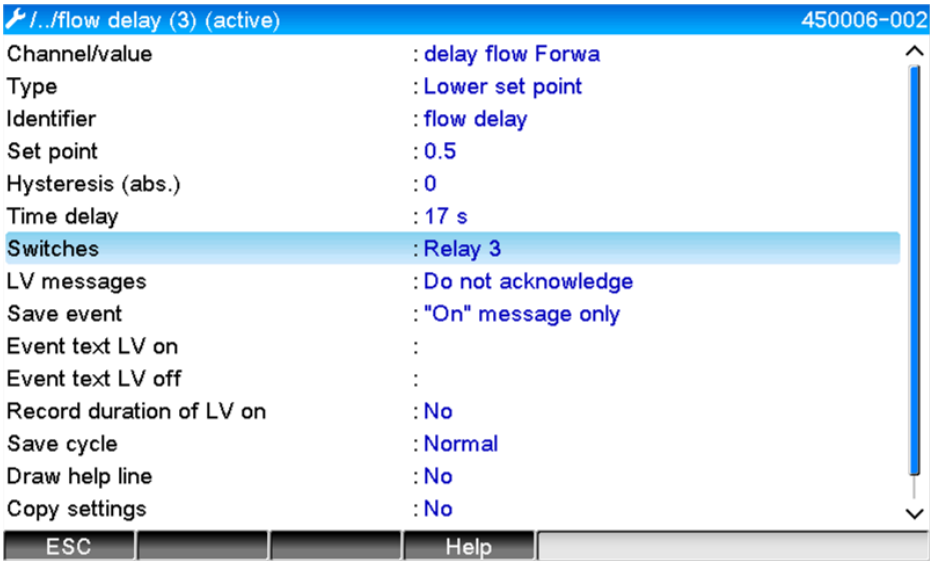
Setting up the limit switch for loss of flow and high flow, please proceed as follows*:
Menu -> Setup -> Advanced setup -> Application -> Limits -> Add limit value



*Pasteurized Milk Ordinance required

Setting up the forward flow delay for flow divert relay, please proceed as follows*:
Menu -> Setup -> Advanced setup -> Application -> Limits -> Add limit value

Relay 3 – assigned flow alarm/set point. A typical 17-second delay is needed to clear the hold tube after a flow alarm. This might differ depending on application and product. Time delay value must be set based on actual application need.



Note: delay should only be set either in PLC or in recorder

*Pasteurized Milk Ordinance required

For hold tube delay to function, a math channel #8 needs to be created – see example below*
Menu -> Setup -> Advanced setup -> Application -> Maths-> Math 8 (delay flow forwa)

/../delay flow Forwa (8) (active)	400000-007
Function	: Formula editor
Channel ident.	: delay flow Forwa
Formula	: LMT(2;2)
The result is	: Instantaneous value
Plot type	: Instantaneous value
Engineering unit	:
Decimal point	: None
Zoom start	: 0
Zoom end	: 1
► Totalization	
Copy settings	: No
✗ Back	

ESC | Help

2.3.3 SFLR Status indication

*Pasteurized Milk Ordinance required

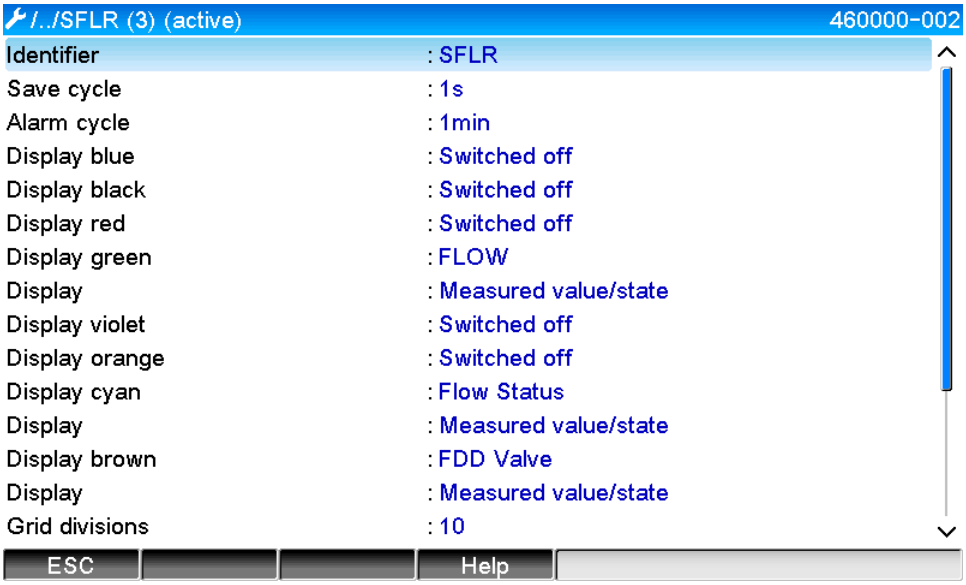
With a mathematic formula the flow signal can be checked if it is within the defined borders (low flow, high flow). The resulting status “GOOD” or “BAD” can be indicated*.
Menu -> Setup -> Advanced setup -> Application -> Maths-> Math 4 (flow status)

/../Flow Status (4) (active)	400000-003
Function	: Formula editor
Channel ident.	: Flow Status
Formula	: if(or(AI(5;2)=0;or(LMT(2;2);LMT(2;3)))=1;0;1)
The result is	: State
Switches relay	: Not used
Description `H`	: GOOD
Description `L`	: BAD
Save event	: Yes
Event Message	: Do not acknowledge
Event text L->H	: flow inside limits
Event text H->L	: flow outside limits
Record duration	: No
Copy settings	: No
✗ Back	

ESC | Help

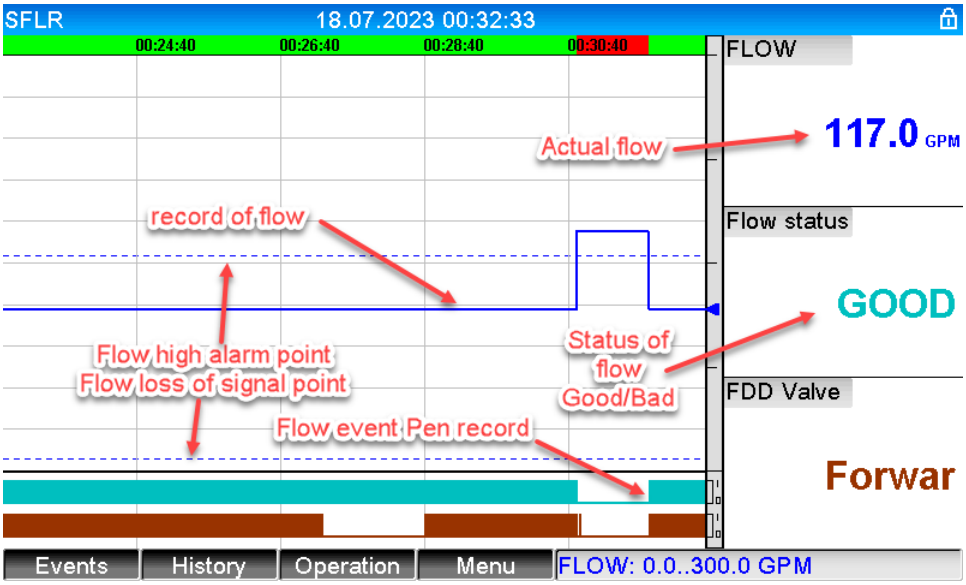
2.3.4 SFLR Visualization

To visualize the flow signal, the “high flow” limit and the “loss of signal” limit, it is recommended to use a display group. According to chapter 2.2.5., define a new group “SFLR” and visualize the flow measurement. The graph will show all needed information including measured flow signal, flow signal status (green/red). Analysis 1 is optional if flow totalizer function is used.



*Pasteurized Milk Ordinance required

After completing the setup, following up the visualization will display the information as shown below*:



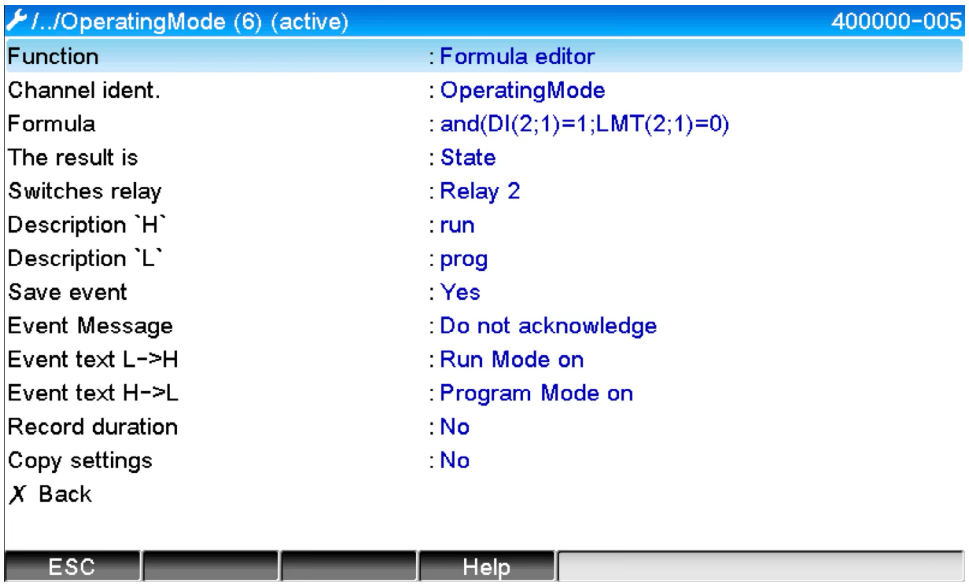
2.4 Setup protection

*Pasteurized Milk Ordinance required

For PMO applications, the changing of the setup (all parameters) need to be secured against accidental or intentional modification by configurating digital input #1 as a “setup lock.” Activation of the setup lock in Memograph M RSG45 settings*:
Menu -> Setup -> Advanced setup -> Inputs -> Digital inputs -> Add input-add input #1 name it “Lock Setup”

*Pasteurized Milk Ordinance required

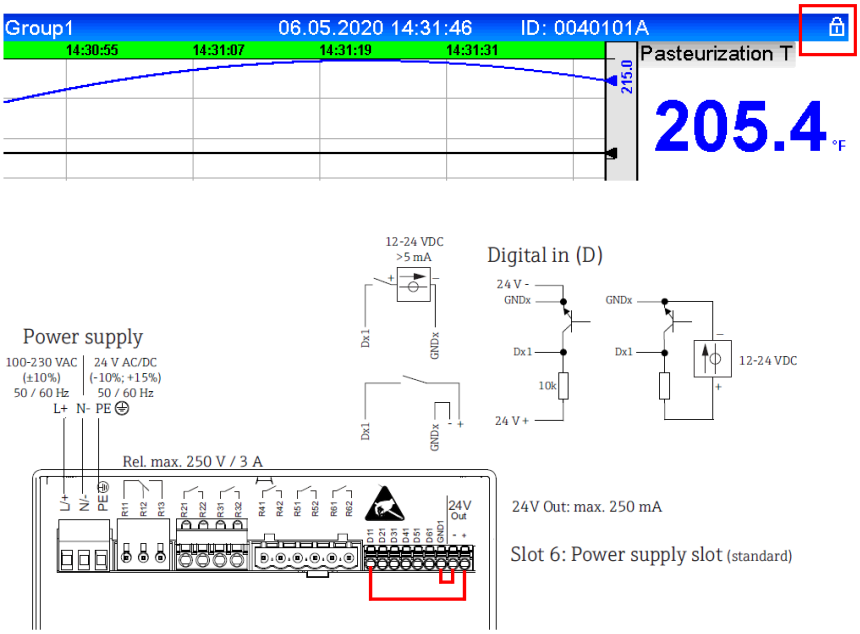
To ensure that relay 2 cannot be activated (forward flow) in programming mode the following math function must be programmed*:
Menu -> Setup -> Advanced setup -> Application -> Maths-> Math 6 (operating mode)



The digital input #1 (D11) is connected to +24V/DC by a jumper (wire bridge) according to the wiring diagram below for digital input D11.

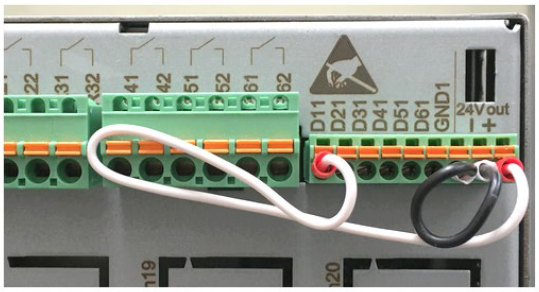
*Pasteurized Milk Ordinance required

During operation, the setup lock is indicated on the top right corner of the display*.



Setup protection - wiring diagram

Ground (-) bridge -> black wire
Protection jumper (+) to D11 -> white wire



*Pasteurized Milk Ordinance required

Setup protection - wiring (example)*

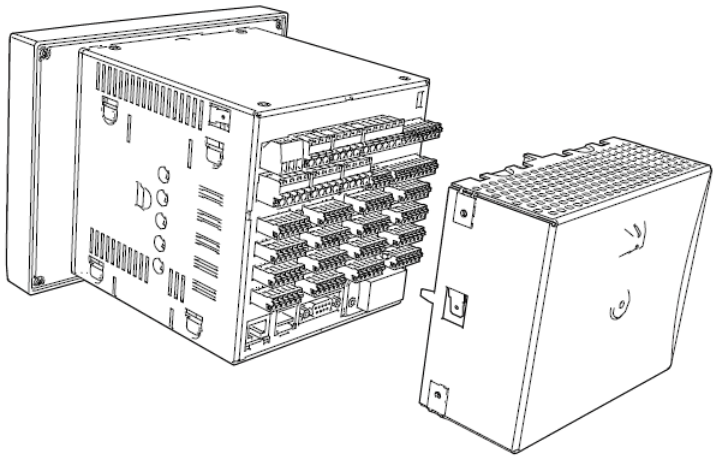
Configure event messages (the messages will appear in the audit-trail when the jumper is closed/ opened) according to your needs.

In addition to this hardware protection, only a user with access rights as administrator can change the setup (FDA user administration needs to be enabled). ***Exception:*** the temperature set-point of the temperature monitoring can be selected during operation by a user of the role “main user,” see chapter 3.2.).

2.5 Terminal cover

*Pasteurized Milk Ordinance required

After commissioning, the device and wiring and all setup settings are finished, the hardware protection jumper (see above) is connected and the complete terminal block of the device are covered by Memograph M RSG45 terminal cover for panel and can be sealed with a regulatory seal like shown in the picture below.*

Description	Order No.
Terminal cover can be sealed (for panel-mounted device) An optional terminal cover is available to prevent tampering at the device terminals and terminal temperature measurement.  	XPR0011-A5

RSG45 terminal cover

Terminal cover mounted on Memograph M RSG45

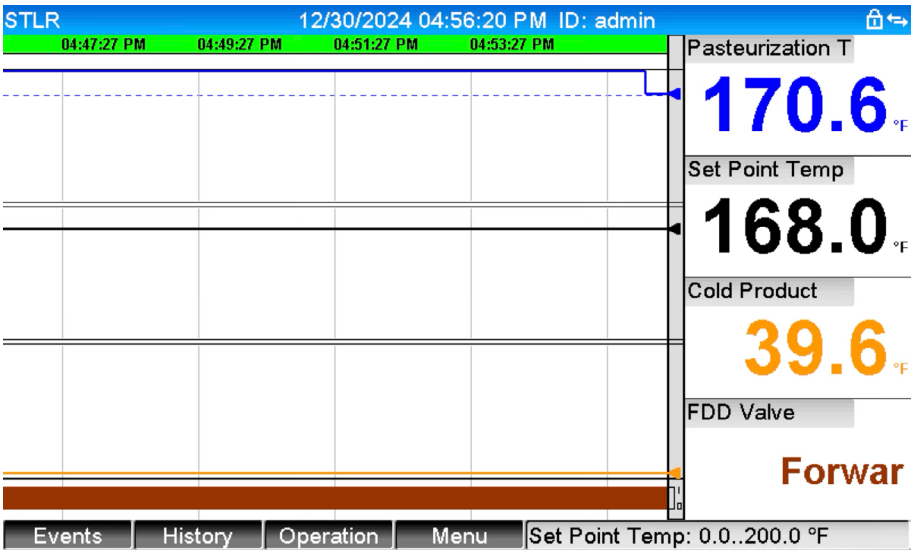
Terminal cover on Memograph M RSG45
zinc diecast version

Fixing screw with hole for regulatory seals

3 Operation

3.1 User Login

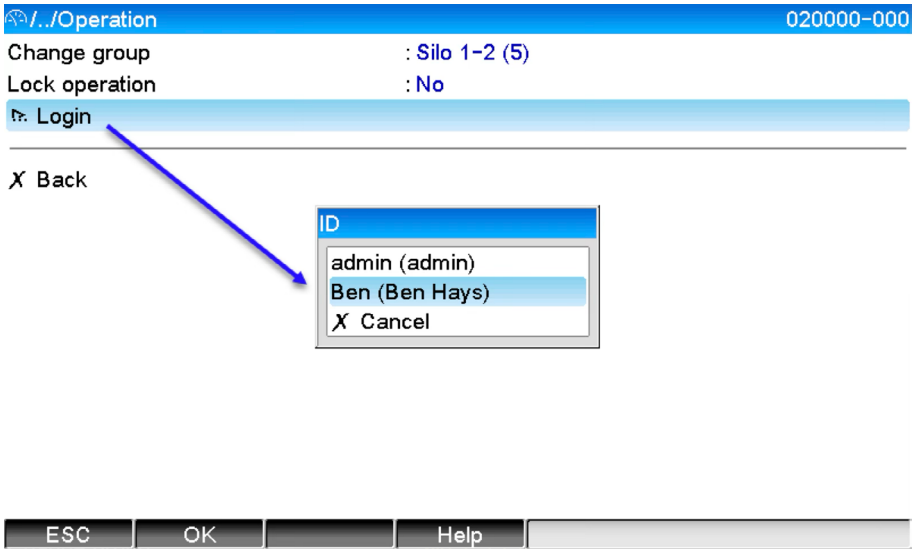
During operation when no user is logged in, only the basic display function is available, like display of the measured values, device information and diagnostics.
No further input options or interactivity are available. Screen examples are below.



Definition of information on screen: measured values are arranged in up to 10 signal groups (screens) and move between screens by swiping left/right.

Navigation buttons:
- Esc – move backward in menu
- Events - takes you to event log
- History – used to search older values
- Operation – takes you to log in screen, or when logged in, to enter text, select setpoints (if applicable)
- >>>, <<<< move back forth in history
- OK – accept entry
- Operation (when in history mode) enable time scaling and scroll speed for past values
- Menu – in main user mode, same as operations; in admin mode, provide access to programming and adding/deleting users

Login procedure: press “Operations” and scroll to find your login name, then select.
A selection list of all created users appear for login. For logging in, the operator can select name in drop down menu (managed by administrator). Enter password and get access according to assigned level. The logged in user is indicated in the display header (alternating ID/user name).
All user logins and logouts are traced tamper-proof in the audit trail as shown below.



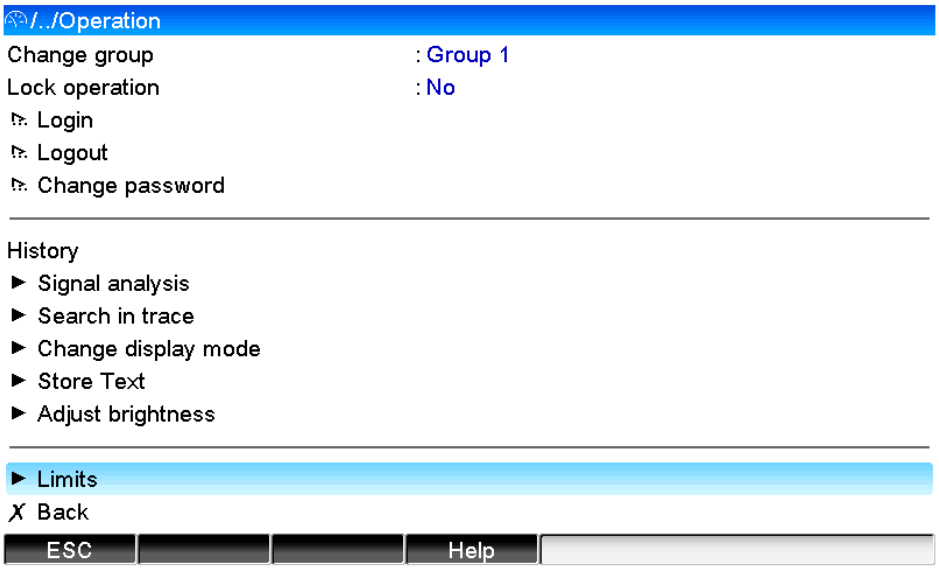
Enter password, click checkmark (enter) and acknowledge (OK) in pop-up, then press ESC.

Alternative login can be accomplished using employee RFID-enabled badges. Simply hold badge in front of reader to log in if set up by company administrator.

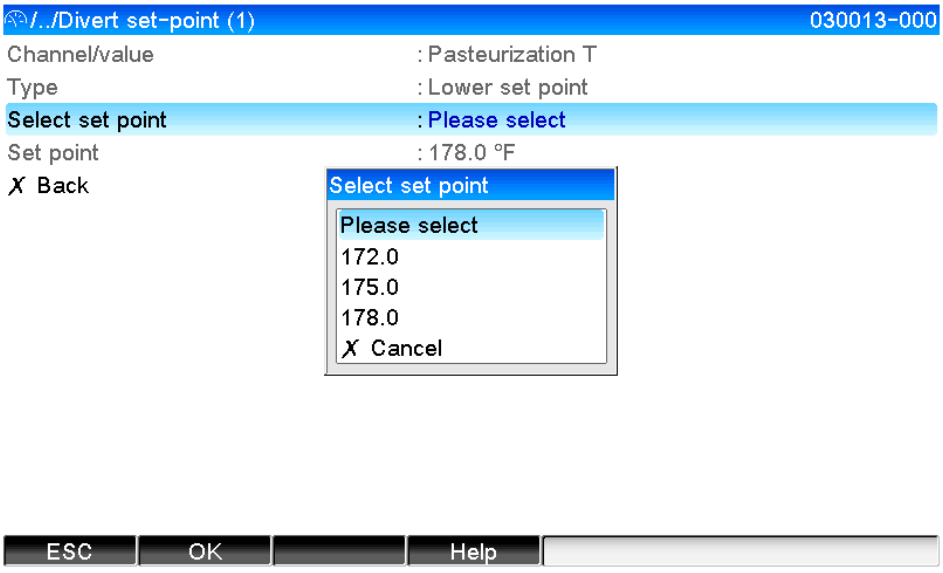
To log out the user, select ***Menu -> Operation -> Log out*** and enter password again. Everyone will be automatically logged out after predetermined time. See section 2.1.2 user administration.

3.2 Select a predetermined set-point (limit)

According to FDA user administration, a user with access rights “main user” can select the divert set-point of a production batch.
Menu -> Operation -> Limits *-> Select set-point*

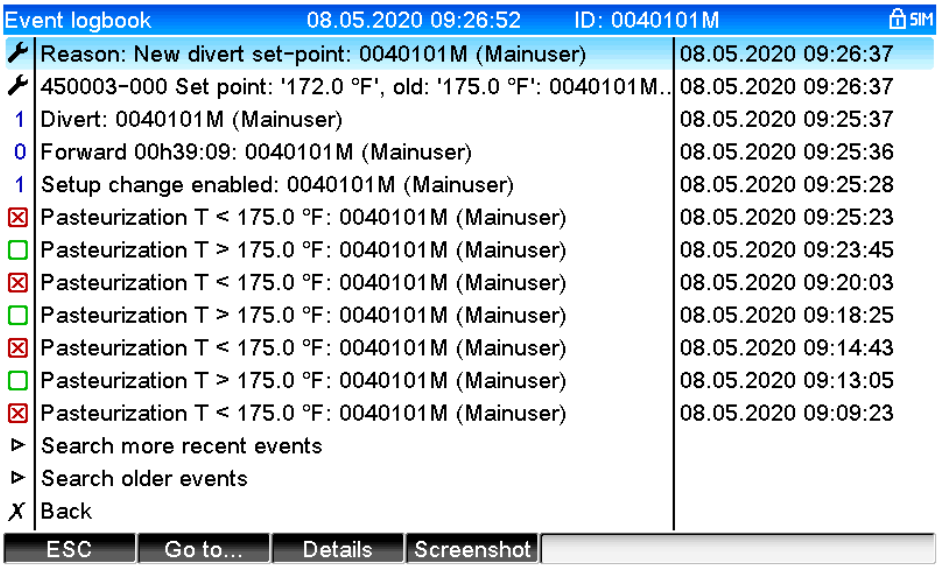


The new limit value can be selected from the predefined default limits (see chapter 2.2.5).



In the next step, the user is asked to enter a text for the reason of the change. The change is valid after selecting ***"Accept set point -> yes"***

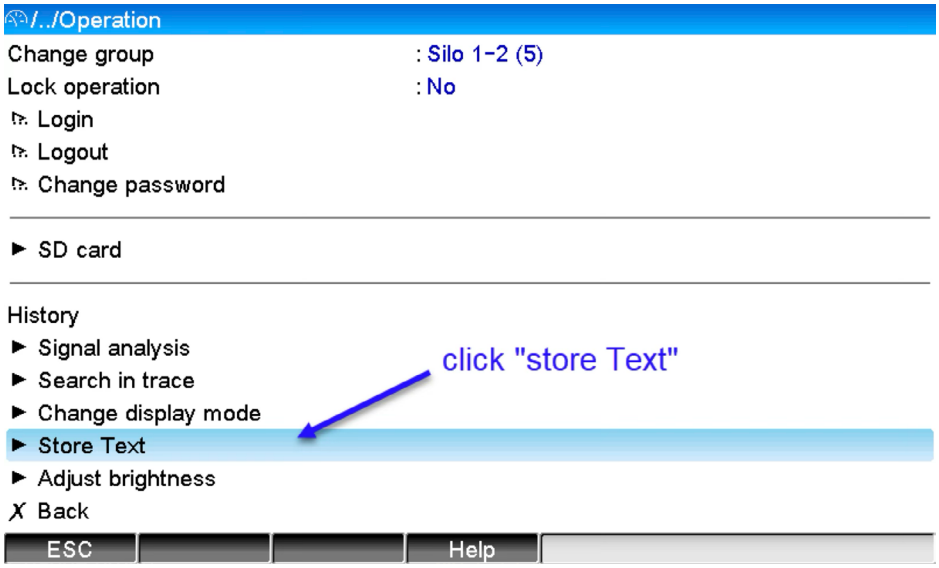
The complete sequence is documented tamper-proof in the audit trail as shown below.



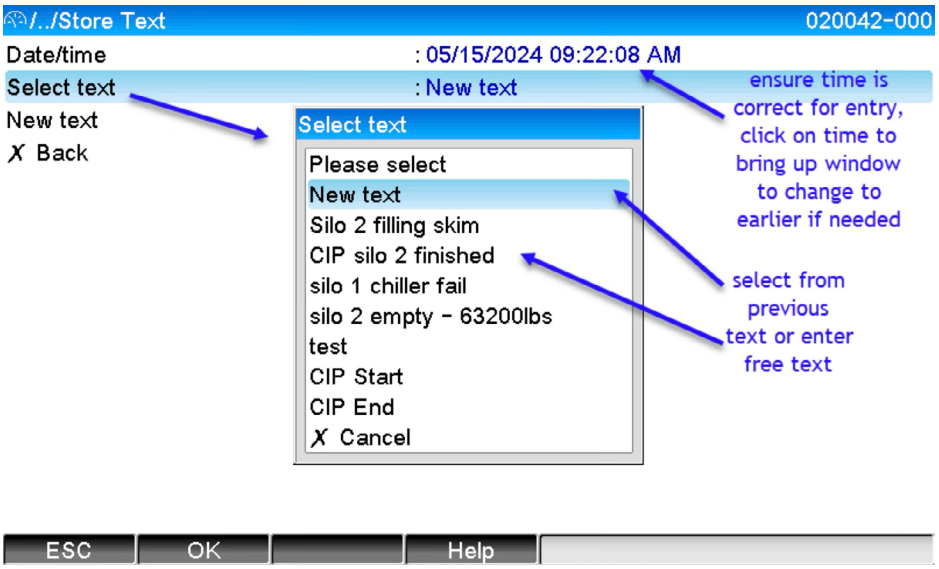
3.3 Post protocol

Administrators and main users have the rights to enter subsequent texts at any time during the production batch. The text will be stored in the audit trail and appear e.g. in the printout of the production batch.
Operation-> store text -> select date time where annotation should show ->select text -> select from pre-programmed or enter New Text. Don't forget to hit "accept"

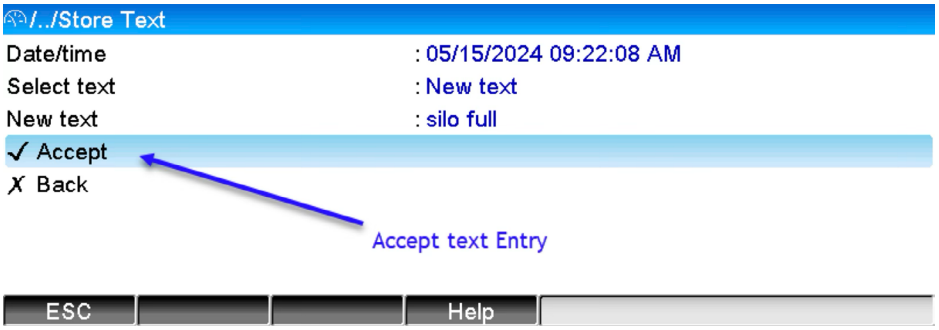
To enter annotation, click "Operations." Then, from this screen, click "Store Text."



Enter free text annotation or select from drop down



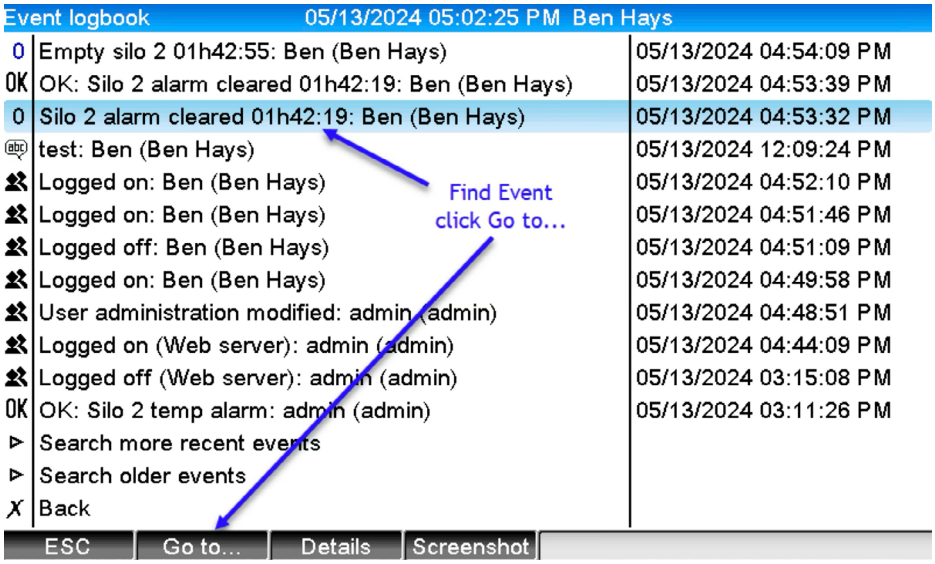
Accept entry



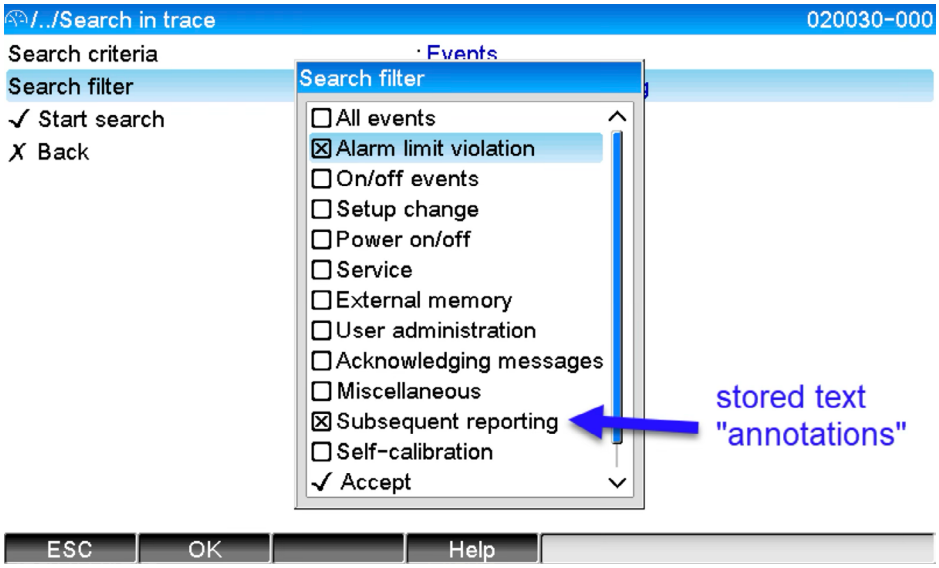
Note: if an annotation was made in error, it cannot be deleted. All entered text will show in the event log. To correct, enter correct information at exactly the same time entry. This correction will then show right after the incorrect entry.

To search/find earlier events to review or enter annotations, there are two methods, via event log (events) or scroll through the chart on screen (history).

Press “Events,” highlight event for review or annotation, click “Go to.” From there, click desired time or event.

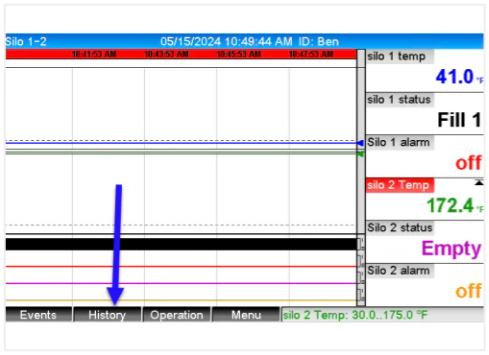


Optionally, to filter event log book, click “Operation” then “Search in Trace” and select desired filters.

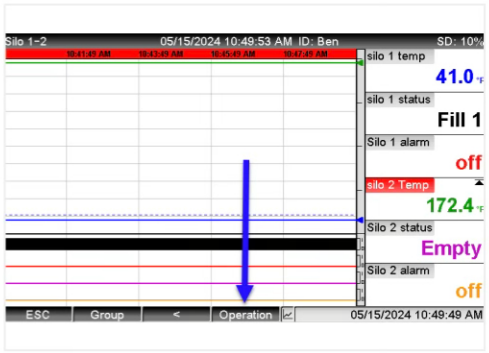


To search/find via recorder screen: find the default screen and scroll speed is the same as recording speed. To see a longer interval on screen, the time scaling can be adjusted to fit application. This is selected as described below. Scroll speed <<< can also be selected by value or ¼...1 page.

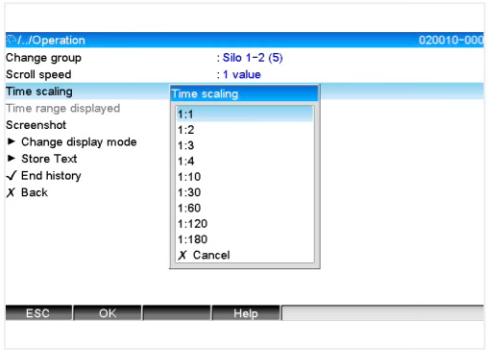
Once event is identified, note the time, click “Operation” and “Store Text.”



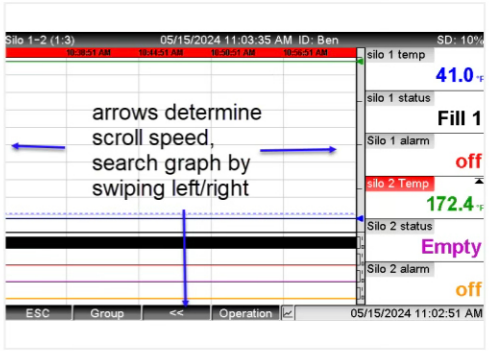
1 Press History



2 Press Operations



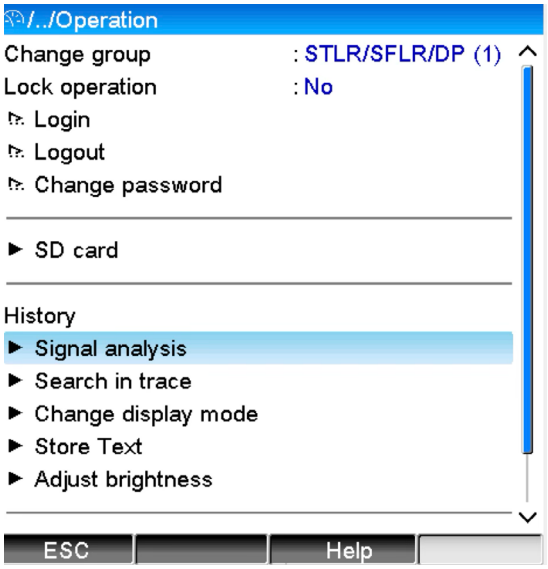
3 Select time scaling (zoom) for history screen eg. 2,4,8hr



4 When in history mode, swipe left/right. If annotation is needed, click operations and follow same steps to enter as annotations for current time.

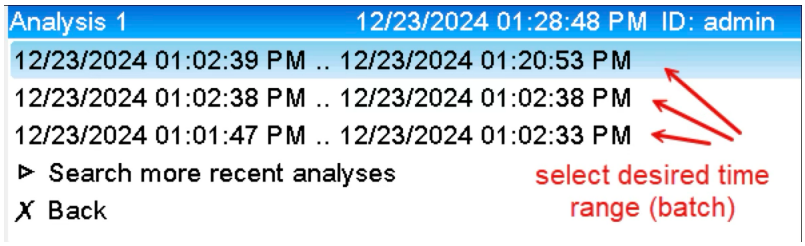
3.3.1 Production analysis

See batch, daily, weekly or custom analysis
Select “Signal Analysis” under operations tab



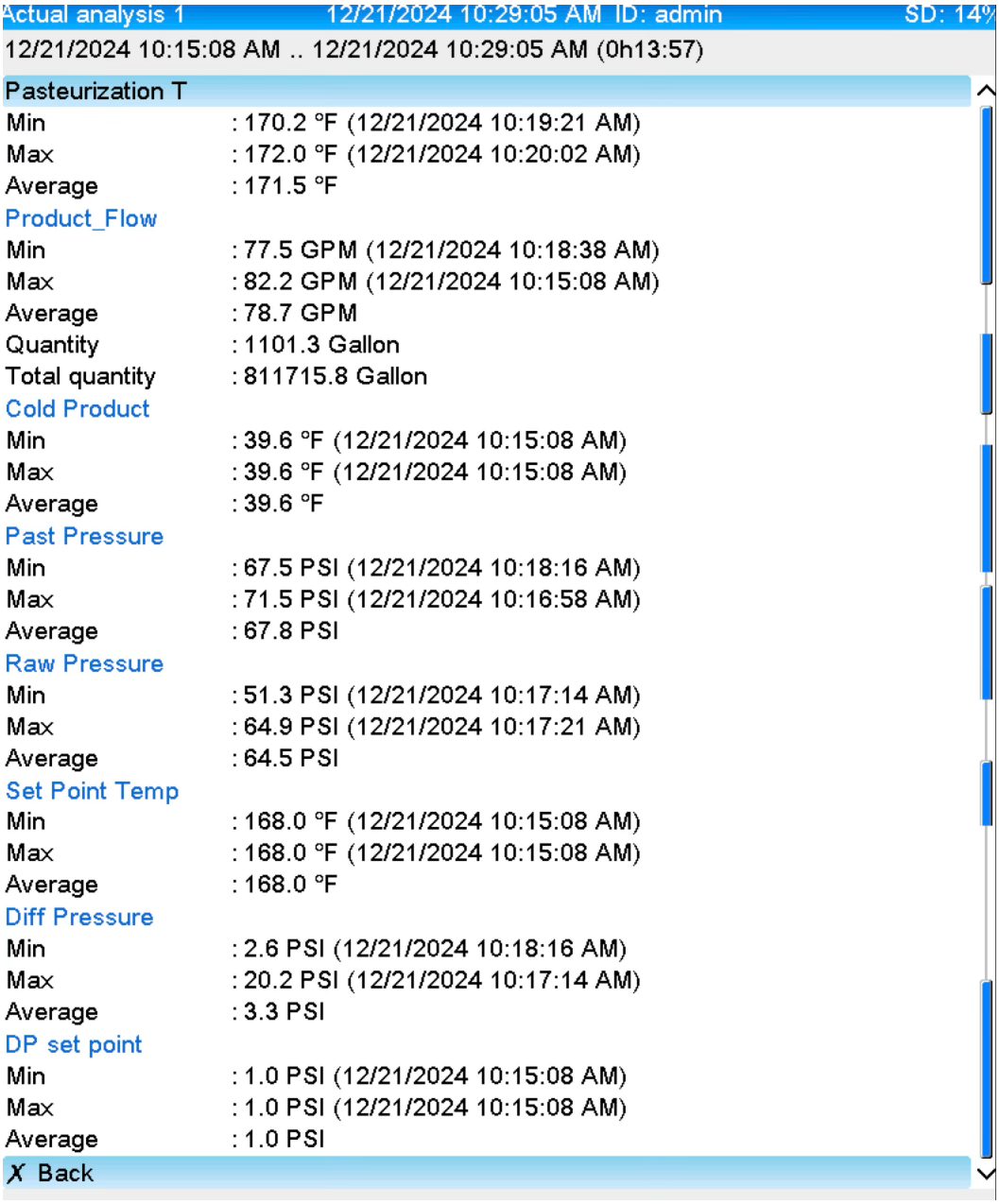
Choose timeframe to view batch, “Actual” is the current running (last batch).
For earlier, select “Search.”

Select Analysis 1, start search



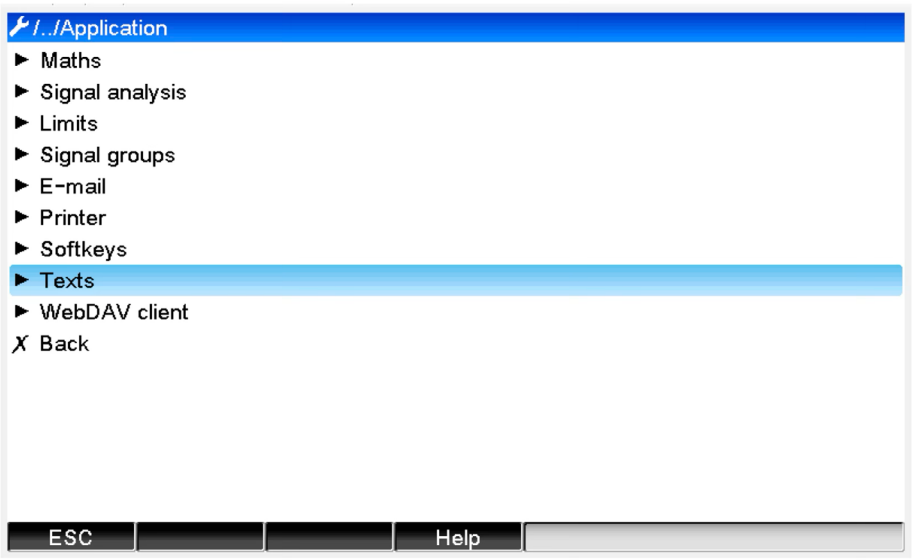
Select time frame for batch data

Example of analysis:
Note: if flow totalizer is used, the total quantity can be reset by administrator under signal analysis in setup menu (program mode)

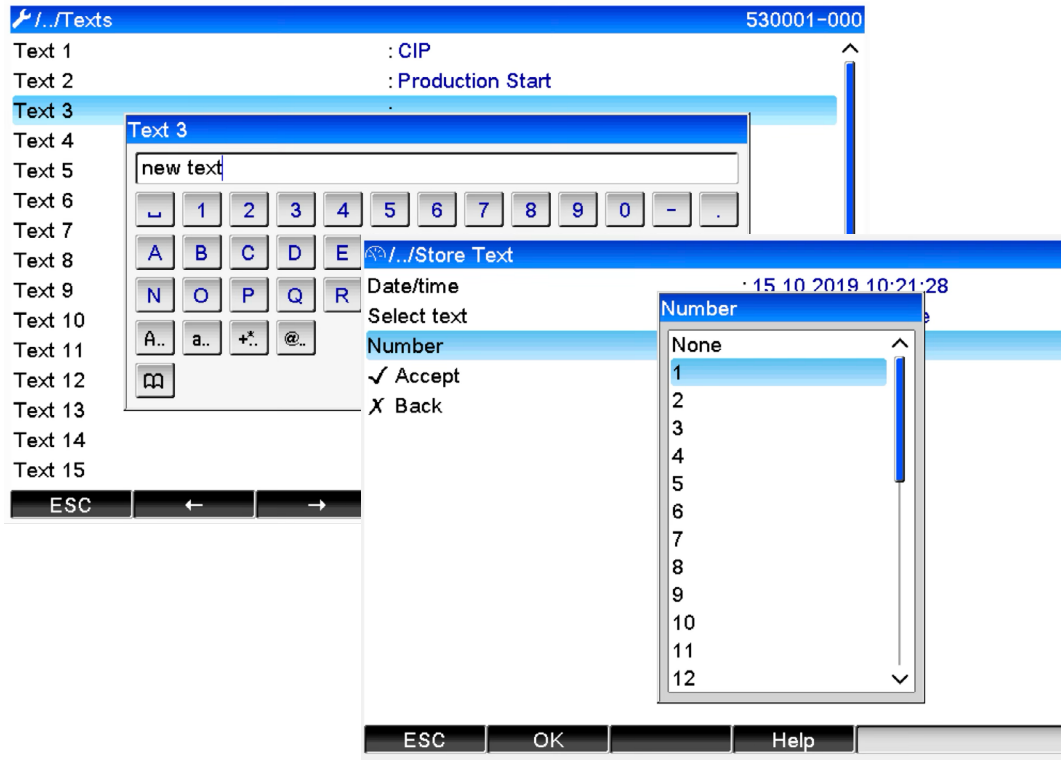


3.3.2 Configuration of pre-set annotation (text)

For easy operation, texts can be stored for selection from a text pool. This has to be entered by the administrator in the setup stage.
Menu -> Setup -> Advanced setup -> Application -> Texts



Menu -> Operation -> Store text -> Select text
Free text or number can be entered. After pressing “Accept text”, the text is entered with time stamp in the audit trail.

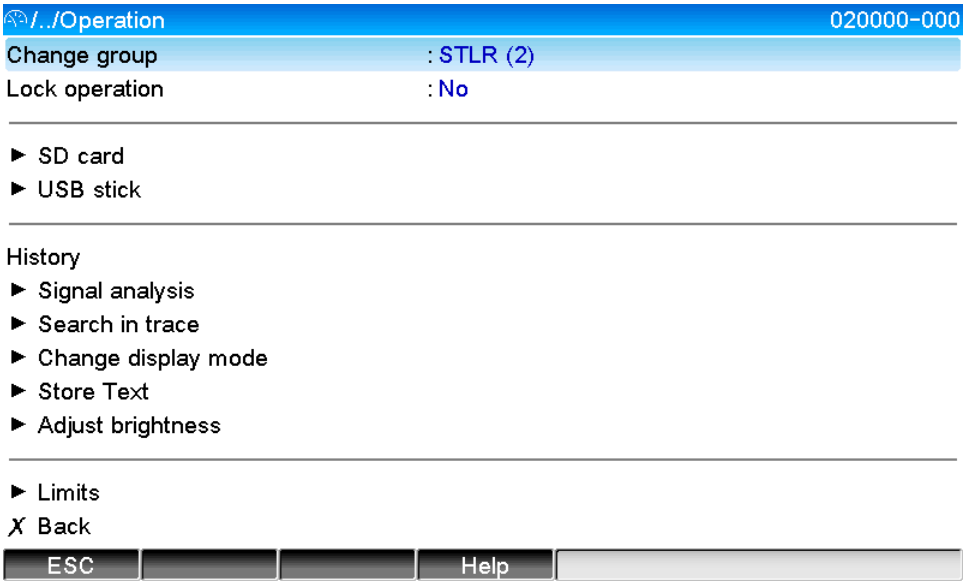


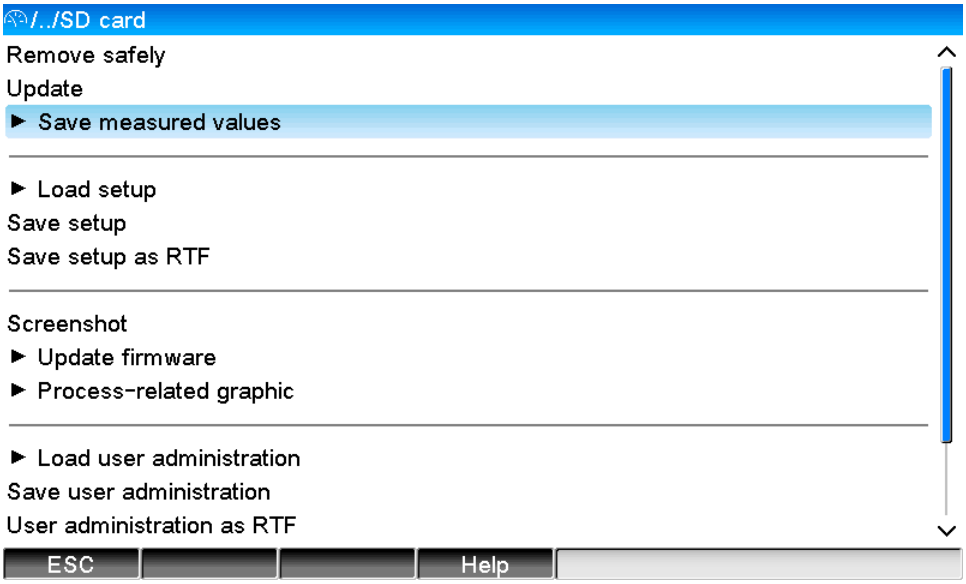
3.4 Secondary data backup via SD card or USB-stick

Note: Primary method for data storage is via automatic data transfer connection to FDM software via EtherNet TCP/IP. However, if desired, a secondary method is to utilize removable SD card or USB stick.

Without affecting the internal RAM memory, data packets are copied automatically block by block (min. 1 x per day, midnight) to the internal SD card. Checksum tests are made to ensure data have been written without any errors.

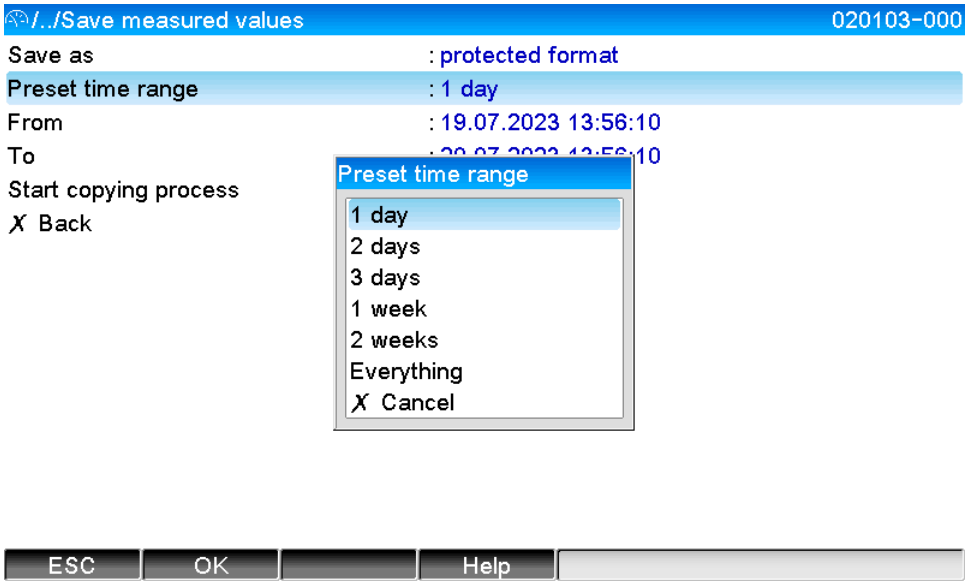
If needed, a manual copy process can be executed e.g. when an SD card or USB stick is used only temporarily:
Menu -> Operation -> USB stick -> Save measured values





Select the time range you want to store -> press "Start copying process"

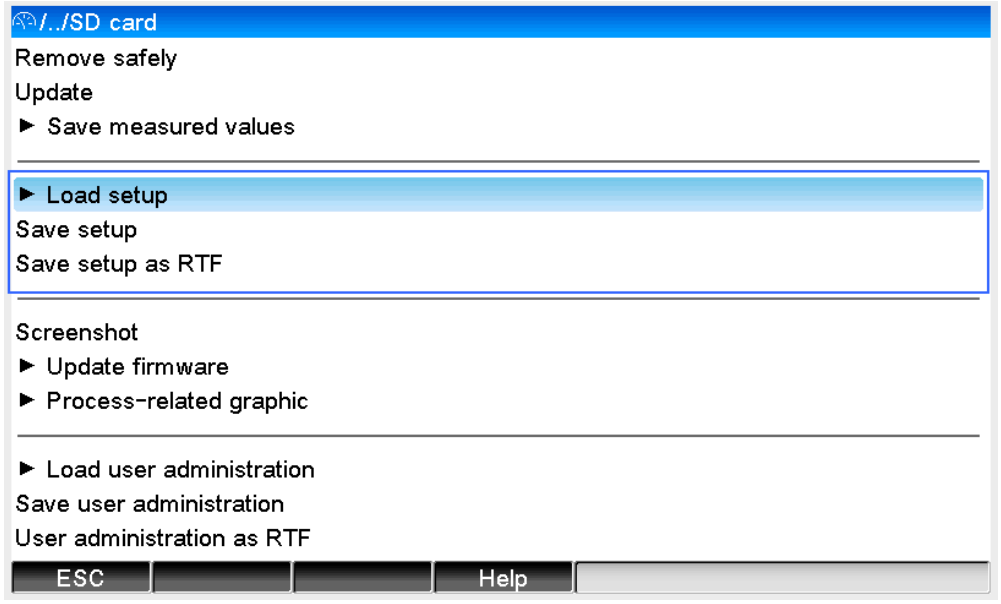
→ The selected data is copied to the storage medium

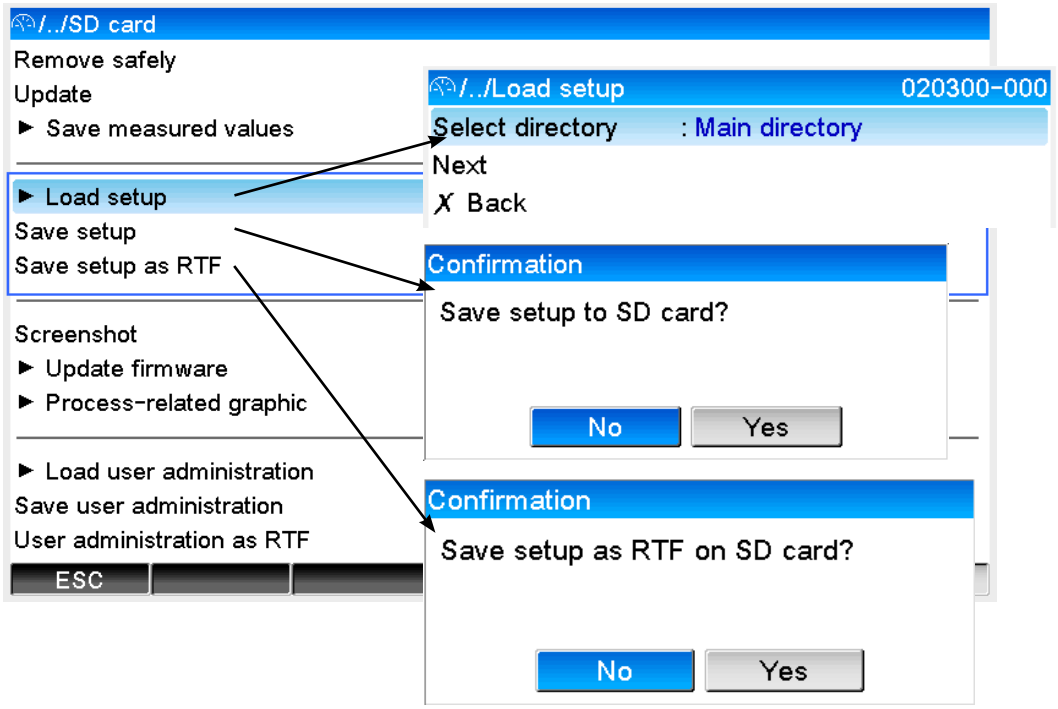


3.5 Setup program management via web server or USB-stick

Memograph M RSG45 supports the management of all settings (e.g. after commissioning or to clone a device with identical setup). A setup file .DEH is saved to the storage medium or loaded from the storage medium. This reduces errors and speeds up procedures if the recorder needs to be replaced or programming duplicated to the second system. Note: The description below shows procedures via touchscreen. The parameter save function is also available via the web server; see screenshot further down.

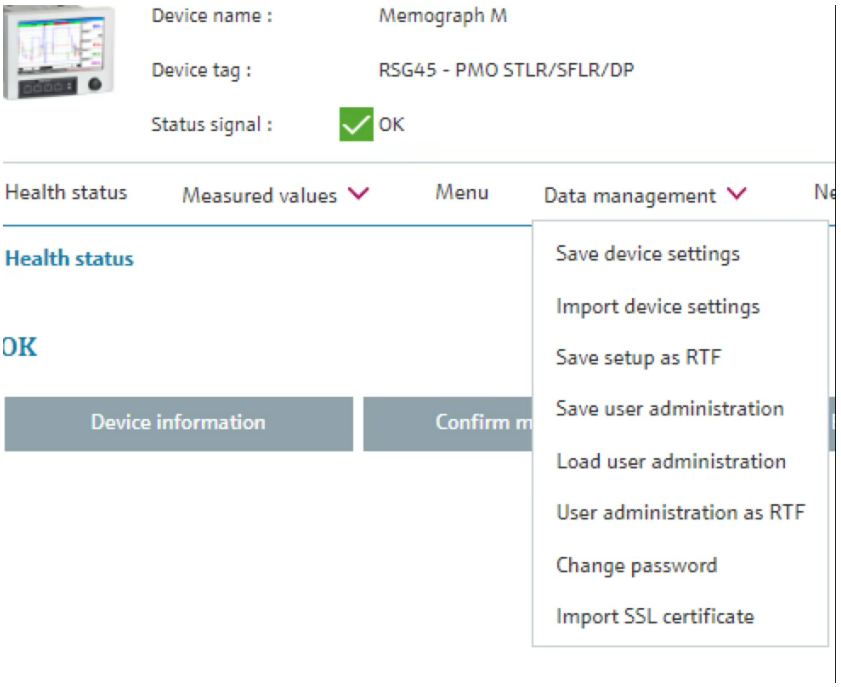
Menu -> Operation -> SD card (or USB stick) -> Load setup / Save setup





To document the completed commissioning, a text file can also be created in *.RTF format where all parameter settings are listed. This file can be saved on USB stick or computer via web server and used for archiving (e.g. on the company server).

Image below shows same functionality of saving/importing set-up using web server.

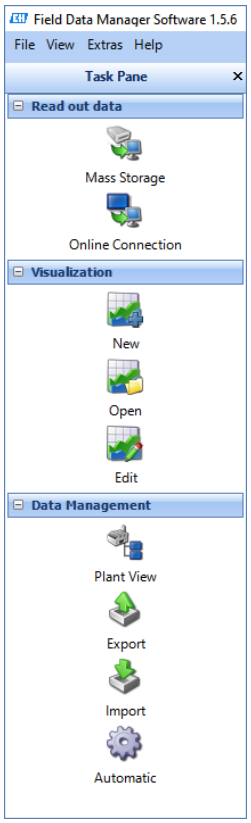


4 Data analyzing and storing with FDM Field Data Manager software

Field Data Manger is the software to read out recorded data from Memograph M RSG45, generate customer specific reports (e.g. for batch documentation) and manage recorded data. The data can be stored in databases and shared for validation purposes. With FDM, the customer receives a software tool that makes it easy to meet legal obligations to provide evidence. This chapter gives an overview of the FDM main functions. For details, refer to the FDM user manual. All settings, operation, reporting and printout are documented there. The following chapter gives a quick start and data access overview.

4.1 Overview

Field Data Manager (FDM) software offers a modern user interface which makes it easy to organize connected devices, connect to them, read out data and set up automatic jobs to create reports, export data, etc.



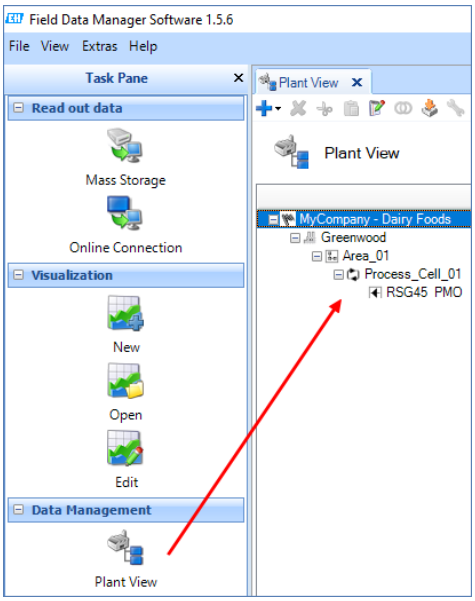
Description of the main menu:

Mass storage – functions to handle data on a disc or card drive
Online connection – connect to a device (Memograph M RSG45) and read out data

New – create a new visualization
Open – open a (stored) visualization
Edit – edit a (stored) visualization

Plant view – manage and organize all devices in your plant
Export – export recorded data as CSV or XLS file
Import – import data from another resource
Automatic – set up automatic jobs (e.g. read out, report, etc.)

4.2 Organize your plant



With the “Plant View” tool you can organize the devices in your plant.

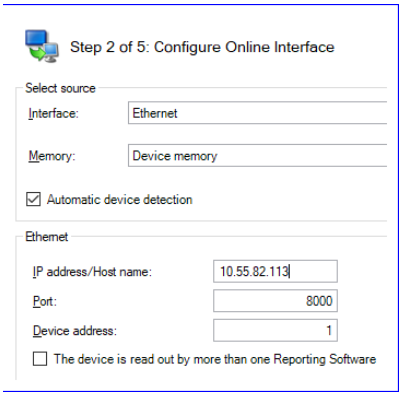
Build up the structure with the elements:
- Company (site)
- Area
- Production Unit (ie UHT 1)
- Unit Memograph M RSG45 device

You can use and rename all elements to fit your naming conventions

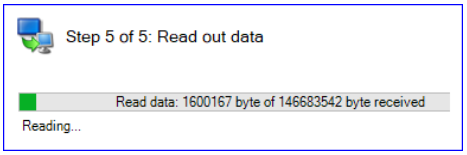
4.3 Set up a connection to Memograph M RSG45 in a PMO application

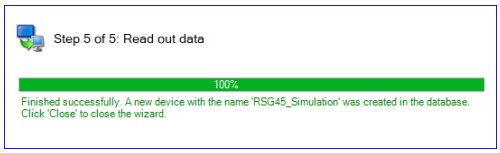
To get connected to a Memograph M RSG45 in a PMO application, it is recommended to use the Ethernet interface. This will provide fast and convenient data transmission.
Connect the Ethernet RJ45 jack on the back of Memograph M RSG45 with your company network or with your laptop by a point-to-point connection.

Select “Online connection” and you will see the plant as defined. Click on “New unit” (resp. how you named Memograph M RSG45) and follow the connectivity wizard step-by-step. You have to enter the IP-address of the device, port (8000) and device address (1) and remain on the presets.



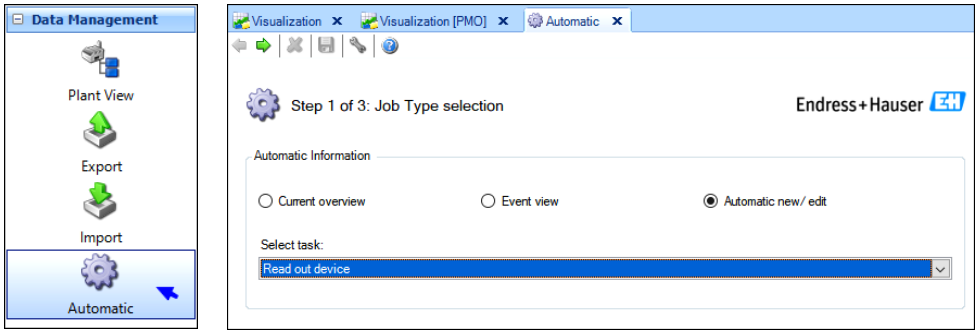
FDM will start to read out recorded data and indicates the result



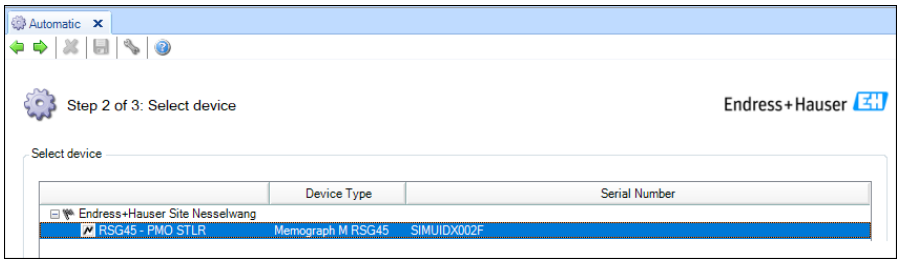


An automatic read out of all recorded data should be activated with the following steps. This will ensure that all current data is automatically transferred to FDM without manual intervention. The FDM software can be closed and the read out is executed in the background.

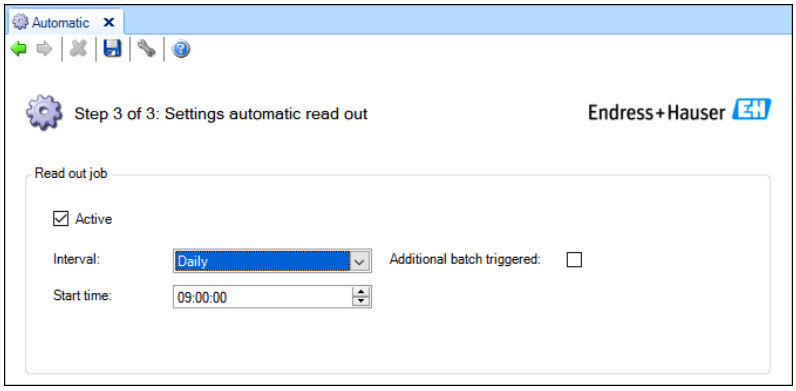
Select “Data Management ***Automatic***” and set up the automatic read out



Select the target device you want to read out

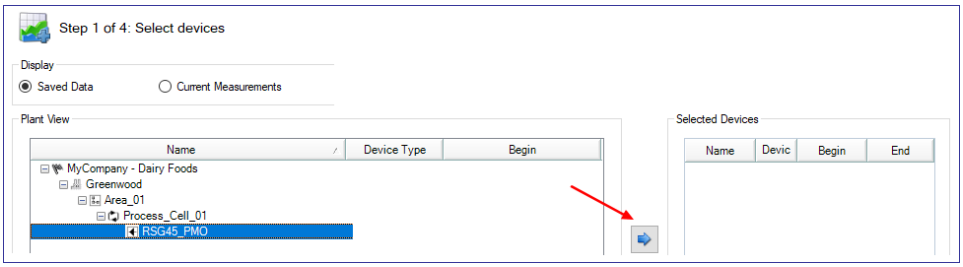


Set the desired read out rate with the time details. We recommend every five minutes for balance between save cycles and current view of data. Note: If communication is lost between recorder and server, this is noted in event log and data transfer automatically resumes when connection is re-established. Memograph M RSG45 internal memory keeps >6 weeks of data.

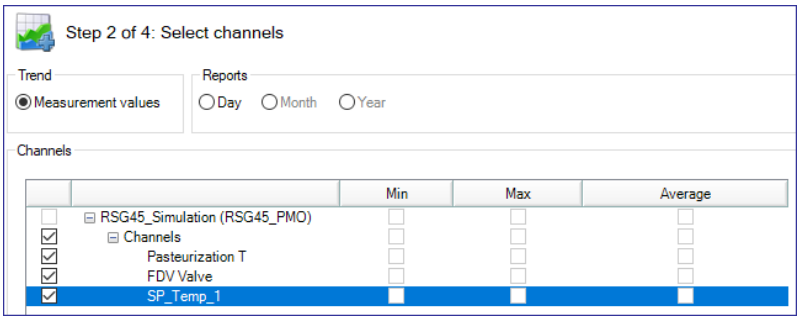


4.4 Visualize recorded data and events

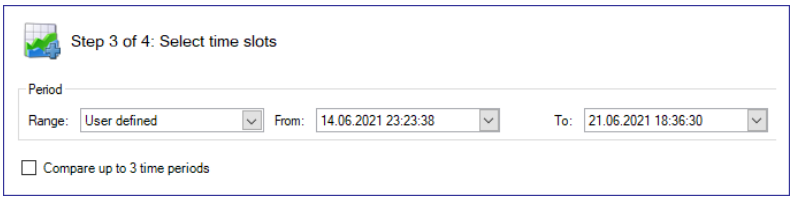
To visualize the recorded data and events (failures, logbook entries, etc.), generate a new visualization or open an already existing one. If you're using FDM for the first time, click on "New visualization," select the device, press the select button and follow the step-by-step wizard.



Select the measured values you want to visualize



Select a time slot e.g. a production batch



The result is the visualization of the recorded data, event log, etc.
The data visualization and data printout can be customized to the requirements defined for PMO applications. For user defined chart settings, click on the measured value.

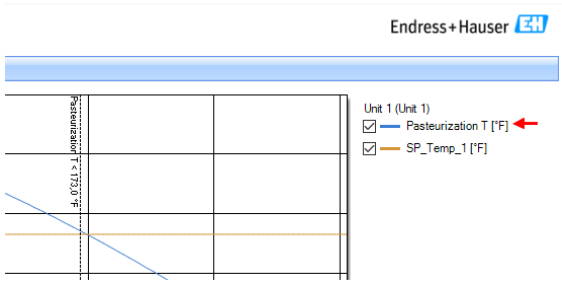
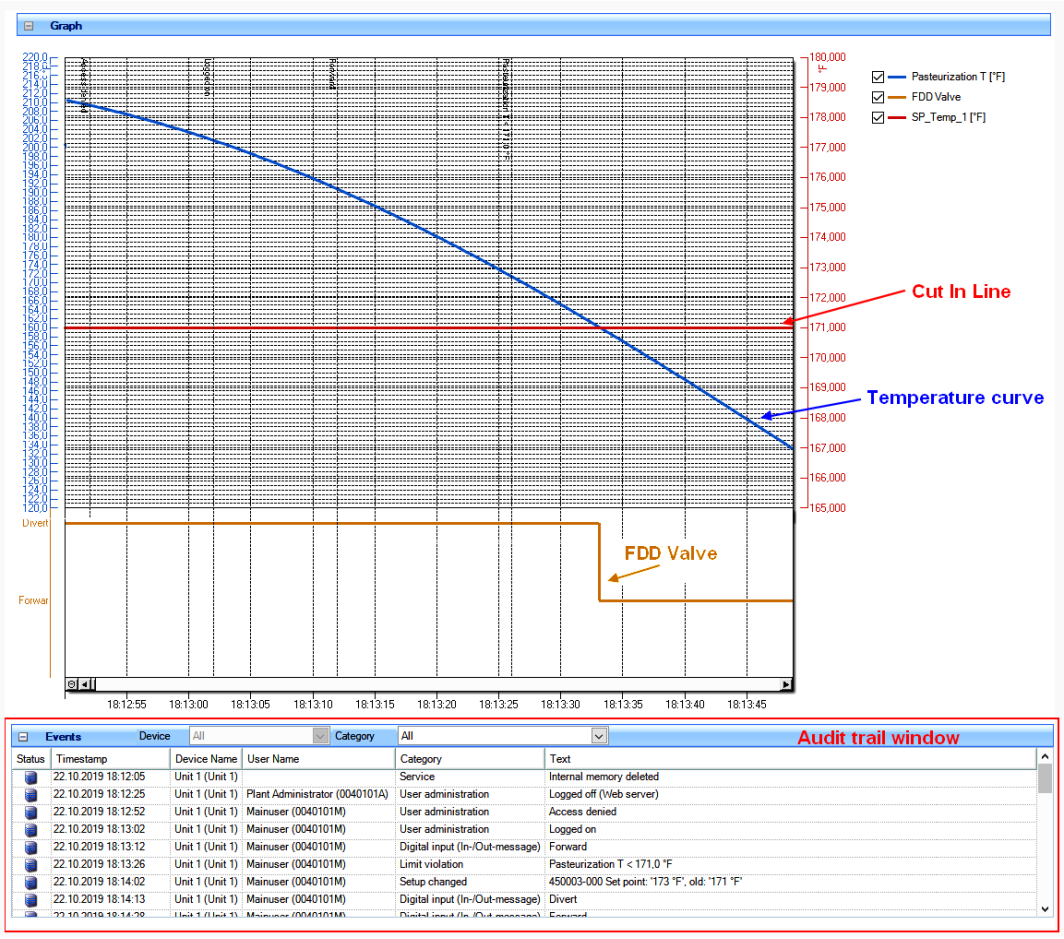
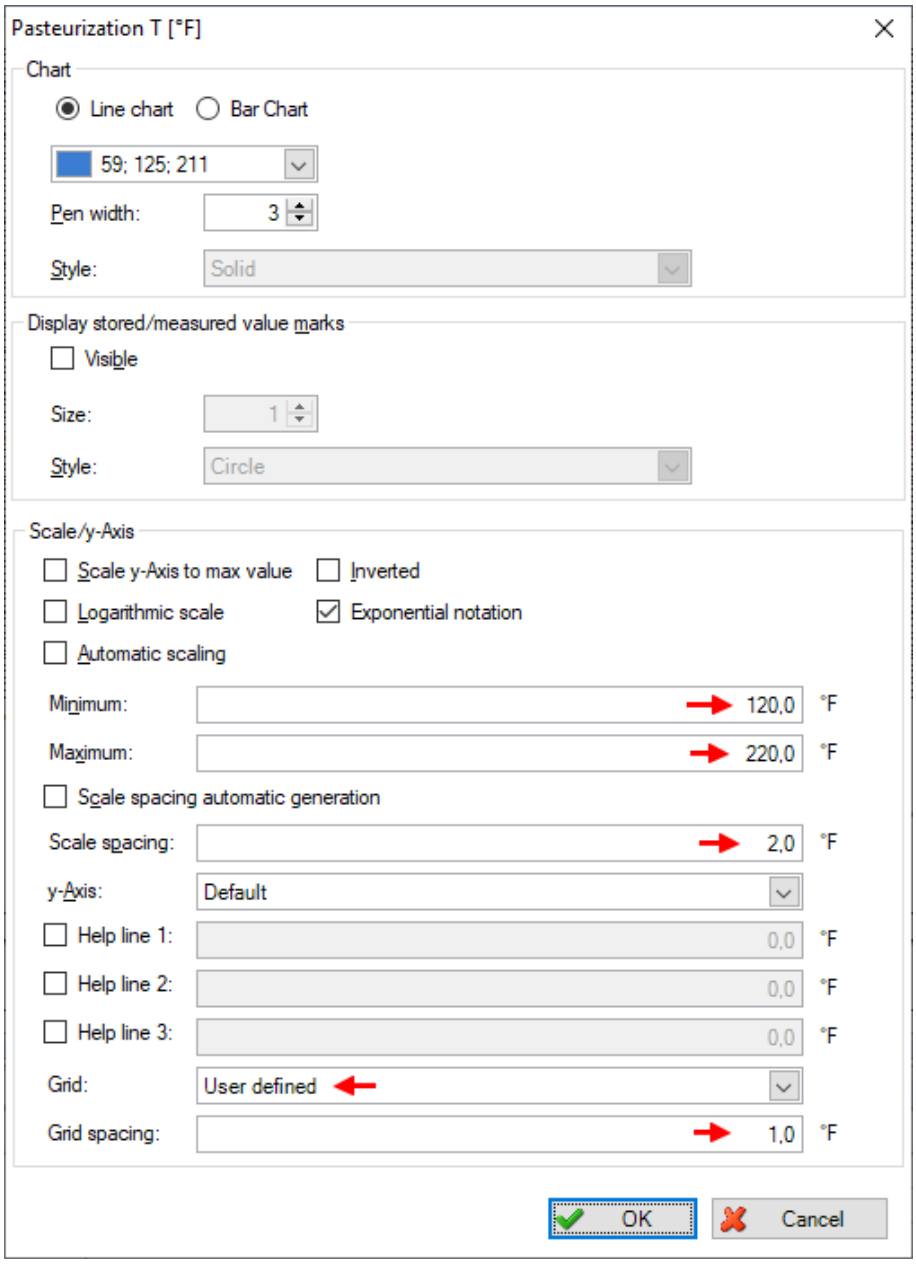


Chart settings for each measurement channel, like display color and pen width, can be set. To set up the grid and scaling for each channel, please proceed as follows: Deselect ***Automatic scaling***, enter minimum and maximum display value (example 120°F to 220°F). Deselect ***Scale spacing automatic generation*** and enter 2.0°F for the scale spacing. For the ***Grid spacing,*** choose ***"User defined"*** and enter 1.0 °F.





Example: FDM view of temperature measurement recording incl. audit trail and divert set-point

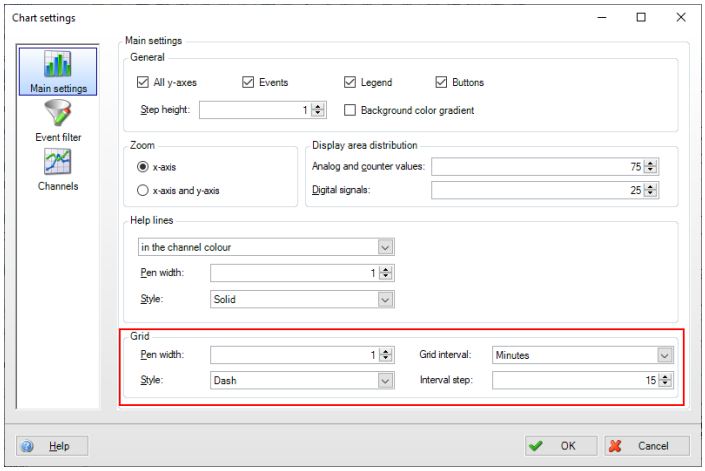
4.5 Creating printouts

Printouts of production batches or customer-specific time ranges (daily logs, 6-hour logs, 12-hour logs, etc.) can be easily generated for documentation purposes.

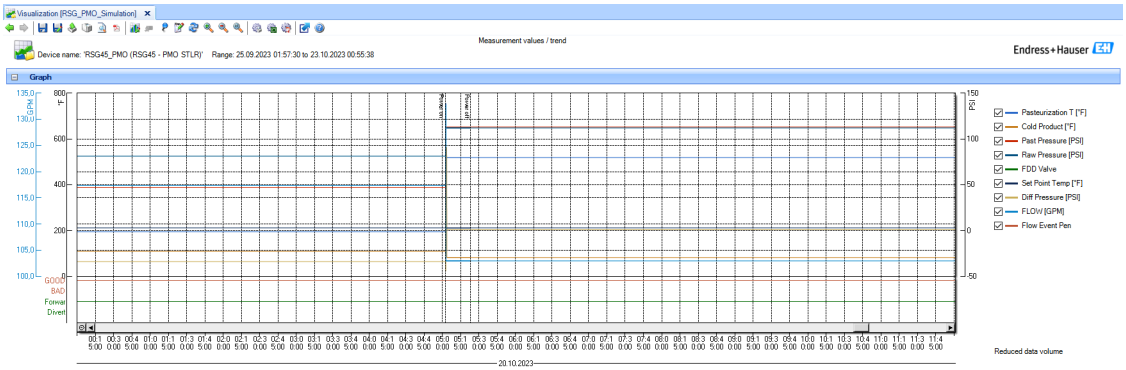
In the dairy industry, it is quite common to generate 12-hour log printouts with a 15 min chart grid. Please follow the steps below for a one-page chart printout.

Open the visualization for the device you want to execute the printout and click on the chart configuration button

Set the x-axis (time-axis) to grid interval “Minutes” and interval step to “15”

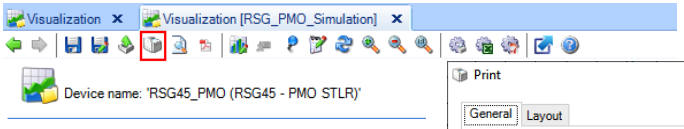


Mark the 12-hour time range in the chart you want to print out and the view will be zoomed to the selected time range. If desired, deselect unnecessary measured values in the control section on the right side.

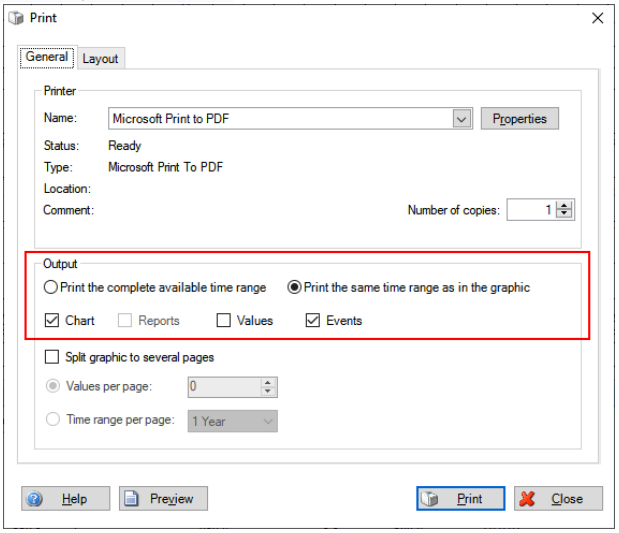


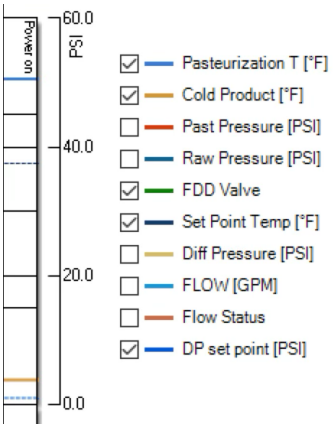
4.6 Setting up templates

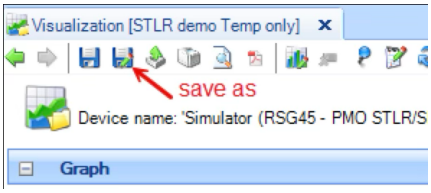
For recorders with many inputs, the visualization can become busy at times. This can be addressed by setting up templates for selected channels. This is beneficial for reporting purposes when the recorder might collect additional information that is not required for reporting purposes or simply to reduce values on FDM chart/screen.

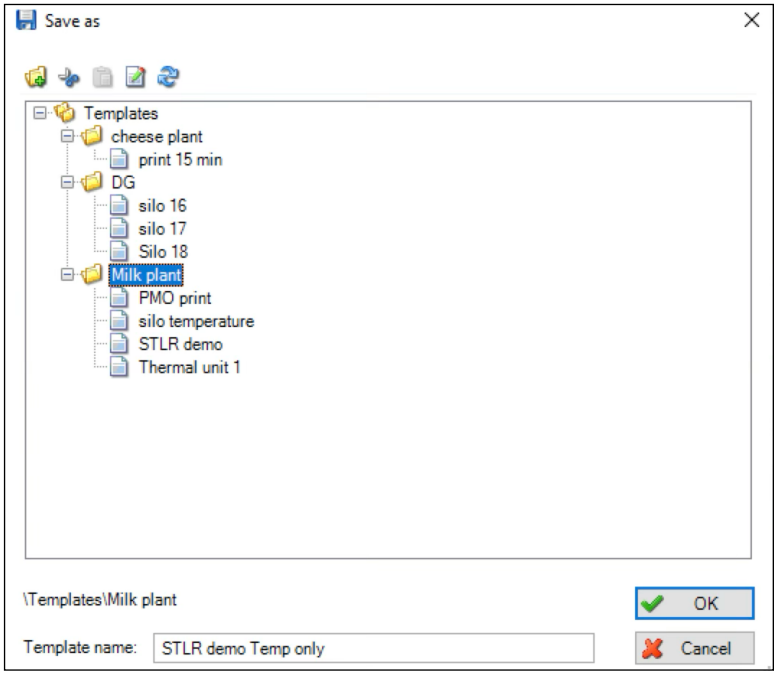


Administrator sets up templates by using “save as” function.
Select channels to include in template, adjust pen width, time scales and other preferences. Then use “save as” function and determine appropriate file name and where in file tree the template should be located.









5 Supplementary documents

For additional information, please refer to the following supplementary documents:

- Memograph M RSG45 – 7-day Installation Report
- Memograph M RSG45 – How to Enter Annotations
- Memograph M RSG45 – Compliant Solutions
- Memograph M RSG45 – Regulatory Systems Overview
- Memograph M RSG45 – FDM User Guide and Beverage Regulatory
- Memograph M RSG45 – Thermal Processing Dairy Brochure
- Operating instructions: Memograph M RSG45 and Field Data Manager (FDM) (SD03224B/09/EN/01.24-00)
- Memograph M RSG45 – Appendix I
- Field Data Manager Software MS20/MS21

- White paper: *Memograph M RSG45 and FDM FDA 21 CFR part 11 (WP01028L)*
- User manual: *Memograph M RSG45*
- User manual: *FDM (Field Device Manager) software (SD03224B/09/EN/01.24-00)*

All listed documents are available on www.endress.com in the download area: https://www.endress.com/en/downloads.

www.addresses.endress.com

SD03224B/09/EN/01.24-00
(01.25)

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